REGISTRATION 9386-49

ISB'S Front-end PRIA Completeness Screen Draft 3; 10/25/07

EP/	N Receipt Date: 2/22/4 EPA Reg. Number:	938	6-U	٥
	Check List Item	Yes	No	N/A
	Has the PRIA Fee been Paid; is a copy of the check or Pay.gov receipt included in the Submission Package?			
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	ne V		
3	Is a Confidential Statement of Formula (EPA Form 8570 29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	- V		
4	Is a Formulator's Exemption Statement (EPA Form 8570 27) Included in the Submission Package?	0-	!	V
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	V		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	V		
7	Is a Label Included in the Submission Package?	1		
X	Arc Data Included in the Submission Package?	V		
9	Is the Submission an Amendment?		1	

Material Sent for Data Extraction

Reg #9386-U0
Description: New Product
Material(s) Sent to Data Extraction Contractors:
New Stamped Label Dated 12 21 11
Notification Dated
New CSF(s) Dated
□ Other:
Decision #:
☐ Other Action/Comments:
Attach this coversheet to the top of the material or jacket. In must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).
Reviewer: Tracy Lantz
Phone: 703 308 6415 Division: AD
Date: 12 21 11 11 12 21 11 12 21 11 12 21 11 12 21 11 12 21 11 12 21 11 12 21

UNITY STATES ENVIRONMENTAL PROTECTIF" AGENCY

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

EPA Reg.	Date of Issuance:
Number:	DEC 2 1 2011
9386-49	
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<u>भेज्य</u> ्य	THE REAL WATER CONTRACTOR STREET, SALES
Term of Issuar	nce:
Conditional	
Name of Pesti	cide Product:

NOTICE OF PESTICIDE:

x Registration
Reregistration

FENNOSURF 586

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Kemira Chemicals, Inc.

1950 Vaughn Road

Kennesaw, GA 30144

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. D445675) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Make the labeling changes listed below before you release the product for shipment:
 - a. Revise the "EPA Registration Symbol to read, "EPA Reg. No. 9386-49"

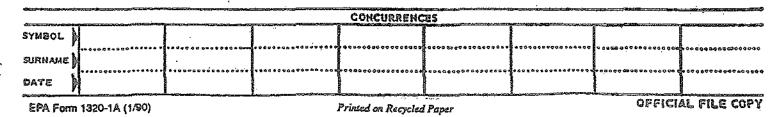
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EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

- b. Revise the Precautionary Statements to include the following: "... Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- c. As per PR Notice 2001-1, revise your First Aid statements such that to be ordered from most toxic to least toxic route of exposure. Revise the order to read "If Swallowed" followed by "If On Skin" followed by "If In Eyes" and "If Inhaled."
- d. Revise the Environmental Hazards Statement to begin as follows: "This pesticide is toxic to fish and aquatic organisms. Do not discharge..."
- d. Revise the "Directions for Use" to begin as follows: "This product must be applied in conjunction 1) an EPA registered sodium hypochlorite product (12.5% a. i.) and 2) a closed delivery system at a pH of \geq 12 to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution..."
- e. In each subsequent instance, indicate that the sodium hypochlorite is an EPA registered product. Also revise to state "... fed into the treatment water systems through a closed chemical feed skid at a pH of \geq 12 only by trained..."
- f. Revise the Directions for Use to be in agreement with PR Notice 2000-5 which requires mandatory language as follows: "...This product is added to the system continuously..." and "...Badly fouled systems *must* be cleaned before initial treatment." (two instances).
- g. Add the following Physical and Chemical Hazards section to your label: "Physical and Chemical Hazards: Direct mixing of this product with sodium hypochlorite solutions and other strong oxidizing and alkali chemicals will release hazardous gases. Only mix with other chemicals or materials solutions following the Directions for Use of this product."
- 2. Submit a one year product specific storage stability and corrosion characteristics studies. Take pH measurements in the same time sequence as the analysis of content and submit this information for review. These studies must be performed in compliance with EPA GLP guidance as per 40 CFR 160. Submit this information by April 1, 2013.
- 3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.



UNITED STATES ENVIRONMENTAL PROTEC

Page 3 EPA Reg. No. 9386-49

Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4. If these conditions including the labeling changes which follow are not complied with, this Registration will be subject to cancellation in accordance with F1FRA section 6 (e).

Your release for shipment of this product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Should you have any questions regarding this letter, please contact Tracy Lantz at lantz.tracy@epa.gov or (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch Antimicrobials Division (7510P)

Enclosure: Stamped Label, DER DP 394455

7510P:T. Lantz:12/21/11:9386-49 ammonia reg notice

ACCEPTED with CQMM /S in EPA Large Dated:

DEC 21 9711

Under the Federal Insecticide, Fengicide, and Rodentiade Act as amended, for the pesticide, registered under EFA Reg. No. 19386-00

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Mc-Too New Product Registration
(PRIA-ASSI)
Fenno aurf 586 (EPA REG. # 9368-UO)
REVISED Product Label 20DEC2011

FENNOSURF 586

Microbiocide for controlling algal, bacterial and fungal deposits in influent water systems and all process water systems used for the manufacture of paper and paperboard products.

 Ammonia (total):
 7.59%

 Inert ingredients:
 92.41%

 Total:
 100%

EPA REG. NO. 9386-XX

EPA EST. NO. 9386-GA-1

KEEP OUT OF REACH OF CHILDREN CAUTION

	FIRST AID
If in eyes	Hold eye open and rinse stowly and gently with water for 15 to 20 minutes.
-	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison control center or doctor for further treatment advice.
If on skin or	Take off contaminated clothing.
clothing	Rinse skin immediately with plenty of water for 15 to 20 minutes.
	Call a poison control center or doctor immediately for treatment advice.
If swallowed	Call poison control center or doctor immediately for treatment advice
	Have person sip a glass of water, if able to swallow.
	Do not induce vomiting unless told to do so by the poison control center or doctor.
	Do not give anything by mouth to an unconscious person.
If inhaled	Move person to fresh air.
	If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth is
	possible.
	HOT LINE
	Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact CHEMTREC at 1-800-424-9300.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Pulp and Paper Mills: Fennosurf 586 can be used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite (12.5% a.i.) to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.5:1.0 product to 1.0 of ammonia to oxidant, and this ratio is obtained by combining 0.6 fluid ounces

of Fennosurf 586 to 1 fluid ounce of sodium hypochlorite (12.5 a.i.). To ensure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Kemira representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment mix 0.6 fluid ounces of Fennosurf 586 to 1 fluid ounce of sodium hypochlorite (12.5% a.i.). Apply solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the process water or stock being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

For continuous treatment mix 0.6 fluid ounces of Fennosurf 586 to 1 fluid ounce of sodium hypochlorite (12.5% a.i.). Apply solution at a rate to obtain at least 1 ppm in excess of system oxidant demand (maximum of 5 ppm) measured as total chlorine in the process water or stock being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by addition of sodium meta bisulfite until the chloramine is no longer detected.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged containers should be placed in overpack containers for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.

Offer for reconditioning, if appropriate. Open dumping is prohibited.

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Density:	Label Date:	
Lot#	Net Wt: XX,XXX lbs.	

Manufactured By

Kemira

KEMIRA CHEMICALS, INC. 1000 PARKWOOD CIRCLE ATLANTA, GA 30339 Dennis Helma

Conypany! Kemira

A532 pand 4631.a product: 7.95% Fennosurf 586

9386-00

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7/14/11 Sent 75 clay letter.

8/17/11 Internal prenecting to discuss proposed chamistry-class 8/22/11 Meet by Keniera to discuss fix

8/22/11 As per Dennis Jent product chemistry class to PBS

9/26/11 for review. We are still waiting for them dute on unreopistered soutce.

9/20/11 enailed 75 day leter

10/11/11 Velma + Trang called Colleen@both # 's + left nessages

She needs to certifine that claim were sent to Frent-End

and needs to renegative. If data here mee MRID

by 10/23 She only needs to renegative for 60 additional

10/12/11 Called both # again + left messages

10/13/11 Conference call by College + Velma her data week to front end on 10/6/11. Velma indicated stack we need additional time for review, we need a total of 120 days for review.

She will We need extension of 60 more days beyond the 12/23/11.

Sind spiritual Dourds like she just sent us the 5 batch one preliminary

Veha Said-new were ord data of METO we will put into ren ewood deen the discuss of Dennis as to whether them are Hill onto studing data rejunctions a get back to her.

Memorandum

10 / 19 / 11 Date:

To: _, Regulatory Manager PM31

Information Services Branch, ITRMD From:

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

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MUP Correspondence

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We expect that it will be approximately 5 days we certificates from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

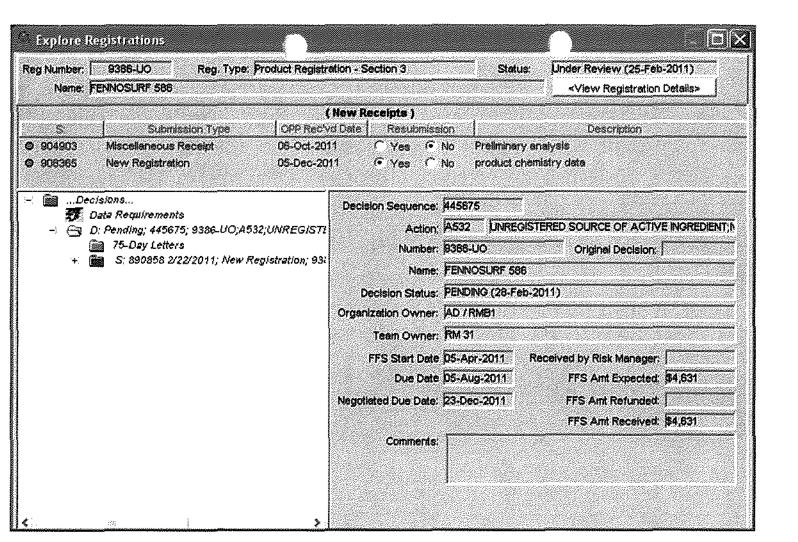
✓ fully accepted submission This is a:

- □ partially accepted submission
- ☐ rejected submission

issues as of 10/20/11 (Dennis, Tran) New duta is only preliminary analysis on end use product Need data on source Do Contenerce call - need date - need renego due dato

Send this detaileto review after con call.

^{*}Product ingredient source information may be entitled to confidential treatment*

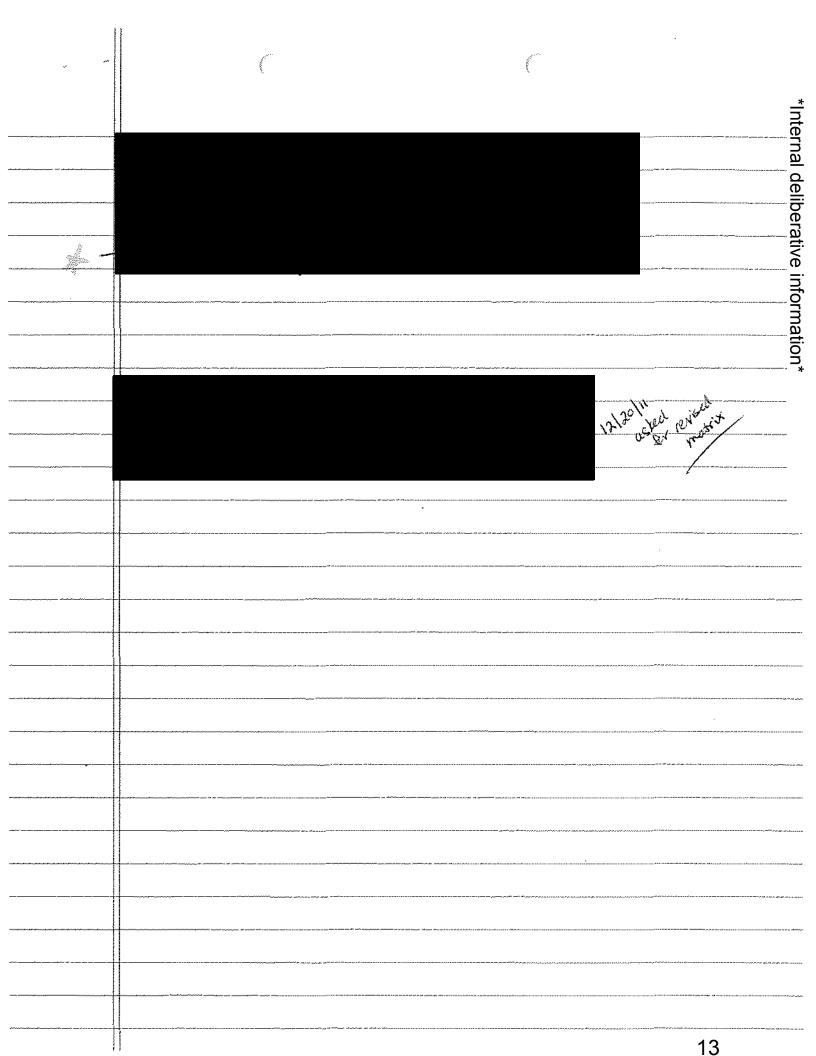


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Me-Too New Product Registration
(PRIA-A531)
Fennosutf \$86 (EPA REG. # 9368-UO)
Product Label 02/11/2011

FENNOSURF 586

Microbiocide for controlling algal, bacterial and fungal deposits in influent water systems and all process systems used for the manufacture of paper and paperboard products.

Ammonia (total):	7.59%
fhert ingredients:	92.41 100%

EPA REG. NO. 9386-UO

EPA EST. NO. 9386-GA-1

KEEP OUT OF REACH OF CHILDREN CAUTION

	FIRST AID		
lf in eyes	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.		
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.		
	Call a poison control center or dector for further treatment advice.		
lf on skin or	Take off contaminated clothing-		
clothing	Rinse skin immediately with plenty of water for 15 to 20 minutes.		
	Call a poison control center or doctor immediately for treatment advice.		
If swallowed	Call poisco control center or doctor immediately for treatment advice		
	Have person sip a glass of water, if able to swallow.		
	Do not induce vomiting unless told to do so by the poison control center or doctor,		
	Do not give anything by mouth to an unconscious person.		
If inhaled	Move person to fresh air.		
	If person is not breathing, call 911 or an ambulance, then give an ificial respiration, preferably by mouth to mouth is		
	possible.		
	HOT LINE		
	Have the product container or label with you when calling a Poison Control Center of doctor or going for treatment. You		
	may also contact CHEMTREC at 1-800-424-9300.		

Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Pulp and Paper Mills: Fennosurf 586 can be used as a microbiocide in the manufacture of paper and paperboard that contacts food.

Dosage Rates: When noticeably fouled, apply sufficient product and sodic chlorine residual of at least 1 ppm in excess of the system oxidant demand, rates can be reduced to sub-demand rates from 50% to 80% of system demands the system continuously or intermittently as needed to any area of the system.

ystem oxidant demand (m ed for 5 to 60 minutes eve d on the severity of the p

ice of sodium hypochlorite dant demand (maximum of

neasured as total chlorine in the process water or stock being treated on a continuous basis. The freque deding and the duration of treatment will depend on the severity of the problem. Badly fouled systems a cleaned before initial treatment.

f chloramine is detected in the effluent, it can be neutralized by addition of sodium meta bisulfite the hloramine is no longer detected.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or da containers should be placed in overpack containers for disposal. Spills should be absorbed in sawd sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violat Federal law. If these wastes cannot be disposed of by use according to label instructions, contact you Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Re office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to contamination of water resources.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. E contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Plastic: Triple ris equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in n sanitary land incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. I Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of sanitary landfill, or by other procedures approved by state and local authorities.

Density:	Label Date:		
Lot#	Net Wt: XX,XXX lbs		

Manufactured By

Kemira

KEMIRA CHEMICALS, INC. 1950 Vaughn Road KENNESAW, GA 30144



CC 6/10/2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108-1241 USA

JUN 1 0 2011

Attention: Jeffery M. Thorne Director, Compliance

"me-too" product

Subject:

Busan 1215

EPA Reg. No.: 1448-433

Amendment Application Dated May 12, 2011

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency approves the changes made to the label per the Agency letter dated January 7, 2011.

The label must be revised so the routes of exposure are listed in the same order in both the First Aid and Hazards to Humans and Domestic Animals Sections, organized so that the routes of exposure of most concern (severe routes of exposure) as supported by the toxicity category classification are listed first.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

Marshall Swindell Product Manager (33)

Regulatory Management Branch I Antimicrobials Division (7510P)

Marshall Swinstell

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Buckman

ACTIVE INGREDIENT(S)
Ammonia (total)
INERT INGREDIENTS
TOTAL

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7.59% 92, 41% 100.00%

when Same as 1448-432

KEEP OUT OF REACH OF CHILDREN

CAUTION

	FIRST AID
if in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes Remove contact tenses, if present, after the first 5 minutes, then continue rinsing eye Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing Rinse skin immediately with plenty of water for 15-20 minutes Call a poison control center or doctor for treatment advice.
lf Swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water, if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
lf Inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER
	product container or label with you when calling a Poison Control Center or doctor or going for treatment, also contact, 901-767-2722 for emergency medical treatment information.

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: The pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



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Punglishing and Anties Contact and S. Buckmo Amended, An the vasculish registered times: EAn Rec. May 1448 433

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MtLLS: BUSAN 1215 is used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive exidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates: For Bulk to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

or intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

INDUSTRIAL WATER SYSTEMS: BUSAN 1215 is used for the control of algal, bacterial and fungal deposits in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desafination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

When this product is used to treat sewage and wastewater systems, seawater, and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, and the system water is not sent to a POTW; residual levels of information in the effluent must be monitored and neutralized using on-line monitoring and control equipment.

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteunizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes; effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water process through a closed metered chemical feed system. The system operator must be trained by a Buckman representative in the use of the chemical feed system. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every t to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to t ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

BUSAN 1215

BÜSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsale is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the neares! EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources.

Nonrefillable

5 gals or less

JONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container for equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for f0 seconds after the flow begins to drip. Fill the container % full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for the later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If metal container, do not puncture or burn.

Capacity of >5 gals

CONTAINER HANDLING: Nonrefitlable container. Do not reuse or refill this container. Differ for recycling, if available. Triple rinse container tor equivalent) promptly after emptying. This east follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and lighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment of a mix tank or store rinsate for later use of disposal. Repeat this procedure two more times. Then offer for recycling if available or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If metal container, do not puncture or burn.

Refillable

Larger than 55 gallons

CONTAINER HANDLING: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Clearling the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to refilling or disposal, use a pressure wash as follows: Empty the remaining contents into application equipment or a mix tank. Use a ressure wash system that rinses all Interior sides with water and that is rated at >40 psi and >120F. Pressure wash the container for a length of time that ensures that a ninimum 25% of the container volume of water is used. During the pressure wash, ensure that the container valve is left open for continuous draining. Collect the rinsate and empty into application equipment or a mix tank or store rinsate for later use or disposal. Allow container to drain for 10 minutes after pressure wash is completed.

55 gallons and smaller

CONTAINER HANDLING: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to refilling or disposal, use a triple rinse wash as follows: Empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously. Pour or pump rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this rinsing procedure two more times.

Manufactured by Buckman Laboratories, Inc.

1256 North McLean Blvd., Memphis, Tennessee 38108, USA

(901) 278-0330 or 1-800-282-5626

EPA Est. No. 1448-TN-1

EPA Reg. No. 1448-433

Product Weight 9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health 1 Flammability 1 Reactivity 0

Last Revision

Sec. 1919

1448-433

RELATED FOR (Milk COMMITTEE DEPARAMETERS

illugionis en el el

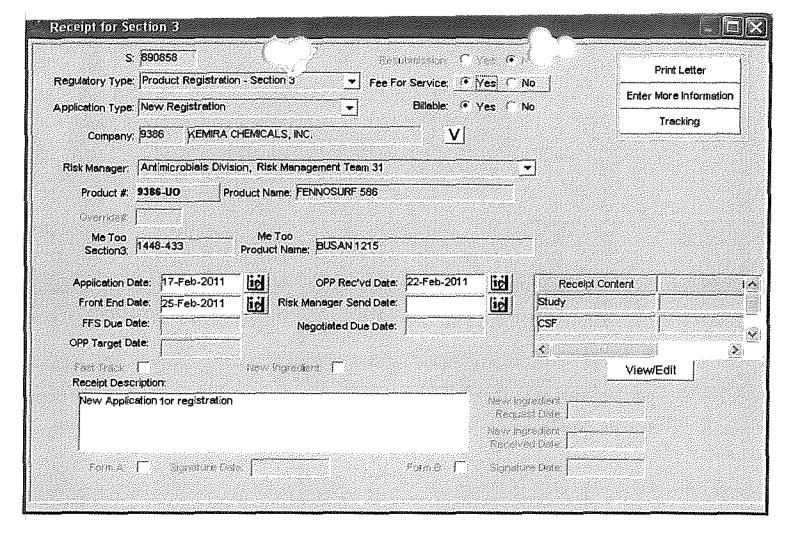
新维尔 海 registered care payer

3/10/2011

Fee for Service



This package includes the following	for Division		
New RegistrationAmendment	● AD ○ BPPD ○ RD		
Studies? □ Fee Waiver?□ volpay % Reduction:	Risk Mgr. 31		
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	890858 9386-UO 2/22/2011		
This item is NOT subject to	o FFS action.		
Action Code: Requested: A531 Granted: A532 Amount Due: \$ 4,631	Parent/Child Decisions:		
Inert Cleared for Intended Use	Uncleared Inert in Product		
Reviewer: Team L	Date: 2-28-11		
Remarks:			



Commercial/financial information may be entitled to confidential treatment

Kemira

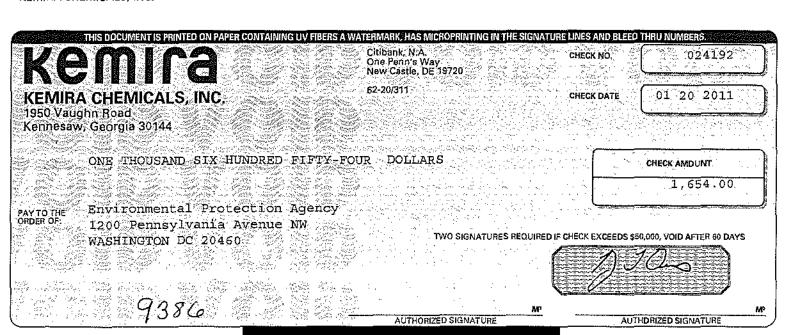
KEMIRA CHEMICALS, INC.

1950 Vaughn Road

Kennesaw, Georgia 30144

INVOICE NO.	DESCRIPTION	INVOICE DATE	GROSS AMOUNT	DISCOUNT	NET AMOUNT
11911	1500502717	01192011	1,654.00		1,654.00
304953	Environmental Protection Ag	ency	1,654.00	0.00	1,654.00

KEMIRA CHEMICALS, INC.



IPO 24 19 2IP

22



RE: Kemira Chemicals Inc -Snyder Colleen to: Tracy Lantz

12/21/2011 09:00 AM Hide Details

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA

2 Attachments





image001.png FENNOSURF 586 DATA MATRIX Revised 20DEC2011.pdf

Hi Tracy,

It was nice speaking with you last night.

I have attached the corrected Data Matrix. Please let me know if I missed anything.

Merry Christmas!

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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Water is the connection

Kemira

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Monday, December 19, 2011 7:02 PM

To: Snyder Colleen

Subject: RE: Kemira Chemicals Inc -

It appears that we will need some revisions to the data matrix. I will be in touch with you tomorrow.

Tracy Lantz



RE: Kemira Chemicals Inc -Snyder Colleen to:

Tracy Lantz 12/20/2011 10:00 AM Hide Details

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA

2 Attachments





image001.png FENNOSURF 586 REVISED APP-LABEL20DEC2011.pdf

Hi Tracy,

I have taken a stab at revising the label Disposal Statement. Please review. I have also attached the Pesticide Application with the packaging size revised.

Look forward to your call,

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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Water is the connection



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Sent: Monday, December 19, 2011 7:02 PM

To: Snyder Colleen

Subject: RE: Kemira Chemicals Inc -

It appears that we will need some revisions to the data matrix.

I will be in touch with you tomorrow.

Tracy Lantz

Re: container containment for 275 gallon tank truck

Nancy Fitz to: Tracy Lantz Cc: Jeanne Kasai, Tony Kish

12/20/2011 08:18 AM

From:

Nancy Fitz/DC/USEPA/US

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

Jeanne Kasai/DC/USEPA/US@EPA, Tony Kish/DC/USEPA/US@EPA

Tracy,

I think you might need to go back to the registrant to get some clarification. Tank trucks generally hold 4,000-5,000 gallons. On the other hand, 275-gallon containers are generally portable composite intermediate bulk containers, like in the attached photo. The label language will be different depending on whether the product is marketed in tank trucks or the 275-gallon totes. Briefly:

1. If tank truck:

- Transport vehicles are exempt from the requirements for "container type" language in §156.140 and "residue removal" language in §156.144 - §156.156. So the label does not need to have any of the new container language in PRN 2007-4.

2. If 275-gallon tote:

- The registrant must identify it as a nonrefillable container or refillable container. Then the label must have the relevant container language from PRN 2007-4.

Let us know if you need more information after you hear back from the registrant. I am only working today and next Wednesday and Thursday, but Jeanne should be around most of the next two weeks.

Nancy Fitz Office of Pesticide Programs U.S. Environmental Protection Agency (703) 305-7385 (phone) (703) 308-2962 (fax) fitz.nancy@epa.gov (e-mail)

Pesticide container & containment web site: http://www.epa.gov/pesticides/regulating/containers.htm



minibulk 2.jpg

Tracy Lantz

Tracy Lantz 12/19/2011 11:09:08 PM

From:

Tracy Lantz/DC/USEPA/US

To:

Jeanne Kasai/DC/USEPA/US@EPA, Nancy Fitz/DC/USEPA/US@EPA

Cc:

Tony Kish/DC/USEPA/US@EPA

Date:

12/19/2011 11:09 PM

Subject:

container containment for 275 gallon tank truck

I am reviewing the label for a product that is marketed only in 275 gallon tank trucks. I just took a quick look at chp 13 and did not see anything specific to these large containers. Would you please point me to the correction section of chp 13 or give am an example of the appropriate language? Thanks

Tracy Lantz





RE: FENNOSURF 586 EPA Reg# 9386-UO

Snyder Colleen to: Tracy Lantz

12/15/2011 03:29 PM

From:

Snyder Colleen <Colleen.Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

I will be available Monday, Tuesday and Wednesday next week. Please call my desk phone first (678-819-4566) then you can call my cell (412-780-7913).

----Original Message----

From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov)

Sent: Thursday, December 15, 2011 3:02 PM

To: Snyder Colleen

Subject: RE: FENNOSURF 586 EPA Reg# 9386-UO

As long as I know you will be in the office those days, I am sure that I will be able to reach you by phone or e-mail.

I don't have specific questions at this time, but want to know that I can reach you next week if needed.

I will send an e-mail if I have a question or concern. I will be in the office thru Wednesday.

(Embedded image moved to file: pic27982.jpg)

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Date:

12/15/2011 02:57 PM

Subject:

RE: FENNOSURF 586 EPA Reg# 9386-UO

Hi Tracy,

Nice to hear from you.

I have very few meetings Monday through Thursday next week so I ask you to propose a time that fits your schedule. I will rearrange my schedule if necessary.

Colleen

----Original Message----

From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, December 15, 2011 2:39 PM

To: Snyder Colleen

Subject: Re: FENNOSURF 586 EPA Reg# 9386-UO

I will send it later today.

Please confirm that you will be available next week and how I should reach you.

I may have some questions or need some corrections to your forms in order to finalize our decision and want to be sure that I know how to reach you.

Thanks

(Embedded image moved to file: pic26869.jpg)

From:

Snyder Colleen <Colleen.Snyder@kemira.com>
Tracy Lantz/DC/USEPA/US@EPA, Earl

To:

Goad/DC/USEPA/US@EPA

Date:

12/15/2011 11:38 AM

Subject:

FENNOSURF 586 EPA Reg# 9386-UO

Hi Tracy and Earl,

At Earl's request, on December 2nd I had sent an email to you with the confirmatory GLP study for OPPTS 830.7000,7100 & 7300 attached. Kemira has had some IT problems and I cannot find that email in my sent folder. May I ask that one of you forward that email to me at your earliest convenience?

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

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DATA PACKAGE BEAN SHEET

Date: 26-Sep-2011 Page 1 of 2

Decision #: 445675

DP #: (394455)

PRIA

Parent DP #:

Submission #: 890858

E-Sub#:

Registration Information * * * Registration: 9386-UO - FENNOSURF 586 Company: 9386 - KEMIRA CHEMICALS, INC. Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855 Risk Manager Reviewer: Tracy Lantz TLANTZ Ediled Due Date: Calculated Due Date Sent Date: Type of Registration: Product Registration - Section 3 Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT; NEW PRODUCT; CITE-ALL DA Ingredients: 005601, Ammonium sulfate(7.59%) * * * Data Package Information * * * Expedile: () Yes 🐵 No Date Sent: 26-Sep-2011 DP Ingredient: 005601, Ammonium sulfate DP Title: CSF Included: () Yes () No Label Included: () Yes () No Assigned To Date Out Organization: AD / PSB Last Possible Science Due Date: 23-Nov-2011 Team Name: CTT Science Due Date: / 2 Sub Data Package Due Date: /2 Contractor Name: * * * Studies Sent for Review * * * Printed on Page 2 * Additional Data Package for this Decision * * *

No Additional Data Packages

Data Package Instructions * * *

Karen: Please review product chemistry data including MRID 483992-01 440/92. This package is incomplete. We are still waiting for them to submit chemistry data on unregistered source of A.I. Please let us know if there are deficiencies with the information submitted thus far.

do cost/bean Wallace will set date

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



United States Environmental Protection Office of Pesticide Programs Agency

Antimicrobials Division (AD) December 15, 2011

DP BARCODE:

394455

MRID:

483992-01, 483992-02, 486371-01, and 486904-01

SUBJECT:

Fennosurf 586

(Name of Product)

REG. NO.:

9386-UO

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use []

OR

End-use Product [x]

INGREDIENTS:

PC Code(s)

CAS Number

Active Ingredient(s):

005601

7782-20-2

Ammonia (from Ammonium sulfate)

TEST LAB:

Eurofins| Product Safety Laboratories

SUBMITTER:

Kemira Chemicals Inc.

GUIDELINE:

OPPTS 830 Series Product Chemistry Groups A and B

ORGANIZATION:

AD\PSB\CTT

REVIEWER:

Earl Goad

APPROVED BY:

Karen P. Hicks

DATE APPROVED: December 15, 2011

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



United States Environmental Protection Agency Office of Pesticide Programs

Antimicrobials Division (AD)

December 15, 2011

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol: 9386-UO

Product Name: Fennosurf 586

DP Barcode: 394455

CODE: (A532) Unregistered source of A.I, New Product; Non-Fast Track

DATE DUE: December 23, 2011

FROM: Earl Goad, Biologist

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

TO: Velma Noble PM#31/Tracy Lantz

Regulatory Management Branch I Antimicrobials Division (7510P)

Applicant: Kemira Chemicals, Inc.

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s): % by wt.

Ammonia (from Ammonium sulfate) 7.59
Other Ingredient(s): 92.41

Total: 100.00

BACKGROUND:

Kemira Chemicals, Inc. has submitted an application for registration of a new end-use product, EPA File Symbol 9386-UO "FENNOSURF 586". This product is used in conjunction with a source of sodium hypochlorite to produce monochloramine as a microbiocide for use in controlling algal, bacterial, and fungal deposits in influent water systems and all process water systems used for the manufacture of paper and paperboard products. The product is produced by an integrated formulation system (i.e., the product contains an active ingredient that is not an EPA-registered product).

The data package included

- 1. A letter from the applicant to EPA, dated February 17, 2011.
- 2. A Confidential Statement of Formula (CSF) for the basic formulation, dated February 17, 2011.
- 3. EPA Form 8570-35 (Data Matrix), dated February 17, 2011.
- 4. A draft label, dated February 11, 2011.
- 5. Three Product Chemistry Studies
 - a. Product Chemistry Group A: Product Identity and Composition (MRID 483992-01)
 - b. Product Chemistry Group B Physical and Chemical Properties.(MRID 483992-02) and (MRID 486904-01)
 - c. Preliminary Analysis (MRID 486371-01)
- 6. Revised basic CSF dated November 15, 2011

FINDINGS:

- Confidential Statement of Formula: The following revisions were made to the original (February 17, 2011) basic CSF during the course of this review
 - a. Under Item #10 "[Total Ammonia]" was added.
 - b. Under #13b, the nominal concentration of Ammonia was added as "[7.59]."
 - c. Under Item #14a the upper and #14b the lower certified limit for the active ingredient for Ammonia.
 - d. The revised basic CSF dated November 15, 2011 was found acceptable.
- 2. Product Label. The product is labeled with Ammonia (total) as the active ingredient at a concentration of 7.59%. However the product as formulated is an aqueous solution of an ammonium salt and inert ingredient.
 - a. It is recommended that the ingredient statement be clarified to represent the form of the product. At room temperature and pressure ammonia is a gas, yet this product is a liquid. It must be made clear from the ingredient statement that the material is aqueous ammonia.

- b. It makes sense that the labeled physical and chemical hazards correspond to the form of the product. Aqueous ammonia is corrosive to metals aluminum zinc, copper and copper alloys such as brass. Additionally, the label must warn against other chemical incompatibilities such as mixing directly with hypochlorites, bleach, and alkali.
- c. It is recommended the "Precautionary Statements" section on the product label, change "after handling and before eating, drinking, chewing gum or using tobacco" to read "after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.
- 3. Product Chemistry Groups A and B. Product chemistry groups A and B data. Please see tables A and B for details.
 - a. Group A Product Identity and Composition. Group A product chemistry data requirements applicable to end-use products have been met.
 - b. Group B: Physical and Chemical Properties: Product chemistry Group B document MRID#:483992-02 is described as a "compilation report" of information rather than a study as defined by EPA GLP standards as found in 40CFR Part 160.
 - In this document descriptive data is given for guidelines 830.6302 Color, 830.6303 Physical State, 830.6304 Odor, 830.6313 Stability, 830.7860 Water solubility. These are acceptable.
 - ii. Non-applicability or Waivers are requested for guidelines 830.6314 Oxidation/Reduction, 830.6315 Flammability, 830.6316 Explodability, 830.6319 Miscibility, 830.6321 Dielectric Breakdown Voltage, 830.7200 Melting point, 830.7570 Octanol/Water Partition. 830.7950 Vapor Pressure, and 830.7220 Boiling point. These are acceptable.
 - iii. Citations are requested with the offer to pay Buckman compensation to use their data including OSCPP 830.6317 Storage Stability, 830.6320 Corrosion characteristics, 830.7000 pH, 830.7100 Viscosity, and 830.7220 Boiling point. While citation of Boiling point may be acceptable, citation of pH, storage stability and corrosion characteristic is not. Since the pH has an influence on the stability of the of ammonia in solution it is recommended that measurement of pH is performed at intervals within the one year GLP compliant storage stability/ corrosion characteristics studies as described as per OSCPP Guidelines 830.6317 and 830.6320.

CONCLUSION:

The revised basic confidential statement of formula (CSF) dated November 15, 2011 is acceptable. Revisions to the label are recommended to address identity of the active ingredient, chemical incompatibilities, and precautionary statements. Product chemistry group A requirements have been satisfied. Product chemistry group B data requirements have been satisfied except for submission of a one year product specific storage stability and corrosion characteristics studies. It is recommended that pH measurements be taken in the same time sequence as the analysis of content. These studies must be performed in compliance with EPA GLP guidance as per 40CFR160.

PRODUCT CHEMISTRY REVIEW

CONFIDENTIAL STATEMENT OF FORMULA

a.	Type of formulation	and source	registration:

•	Non-integrated formulation system	Yes[[No [X[
•	Are all TGAIs used registered?	Yes[]	No [X]
•	Integrated formulation system	Yes [X]	No [1

If "ME-TOO," specify EPA Reg. No. of existing product: 1448-433

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§ t80.940 and 180.950.

Yes [No [X]

Note: All inert ingredients have PC codes.

Note: All Inert ingredients are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated in April 2011 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product:

Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

		Yes [X]	140[]
e. The NCs and CLs are acceptable.		Ye	s [X[No []
f. Active ingredient(s)	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
(Ammonium sulfate	29.5	28.61	30.38)
Ammonia	7,59	7.21	7.96

- g. For products produced by an integrated formulation system:
 - Do all impurities of toxicological significance have a UCL?
 Yes [] No [] Not applicable [X]
 - Have all impurities of ≥ 0.1% in the product been identified?
 Yes [No [] Not applicable [X[

II PRODUCT LABEL

a. The active ingredient(s) s the CONFIDENTIAL STATE			IC) is consister Yes []	nt with No [X]		
Note: The CSF was ammonia, which is th			l concentration	of		
b. The formula contains one	of the followin	g:				
 10% or more of a per 1.0% or more of met sodium nitrite at any a toxic List 1 inert at arsenic in any form: 	hyl alcohol: level:	e:	Yes]] Yes]] Yes[] Yes[]	No [X] No [X] No [X] No [X] No [X]		
c. If "yes" to any of the above footnote indicating this?	ve, does the ine Yes []	ert ingredients s No[]	statement conta Not applicabl			
d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.						
Yes [] No [] Not applicable [X] e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.						
	Yes []	No []	Not applicable	e [X]		
f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information). Yes [X] No []						
Note: Results for a r	minimum of 1 ve	ear from a GLF	-compliant sto	raae		

stability study must be provided.

Table A: Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity	Α	483992-01
		and C S F
830,1600 Description of	Α	483992-01
Materials		and CSF
830.1620 Production Process ²	Α	483992-01
830.1650 Formulation Pro c ess ³	NA	
830.1670 Formation of Impurities ⁴	Α	483992-01
830.1700 Preliminary Analysis ⁵	Originally results from the analysis of	483992-01
	two batches of the product were	(pages 49
	provided. Testing was <u>not</u> conducted in	and 50)
	compliance with GLP Results were	
	reported in mg/L not %wgt/wgt. This	
	was found unacceptable.	
	A – Results of 5 batches conducted in compliance with GLP. All results within certified limits.	486371-01
830.1750 Certified Limits ⁶	A – Standard certified limits were proposed.	483992-01
	A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	
830.1800 Enforcement	A – A copy of a colorimetric method	483992-01
Analytical Method ⁷	("Determination of Ammonia Nitrogen	
	by Semi-Automated Colorimetry") was	
	provided for determining active	
	ingredient content of the product.	
830.1900 S ubmittal of	[Samples are to be provided on a case-	
Samples	by-case basis for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate

See Confidential Appendix A for additional information.

Confidential Appendix A. Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in

Table B: Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is clear, slightly hazy.	483992-02
830.6303 Physical State	Α	The product is a liquid.	483992-02
830.6304 Odor	А	The product has a slight ammonia odor.	483992-02
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal lons	NA	[Not required for end-use products.]	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	The product is not an oxidizer or reducer, and neither are its components.	483992-02
830.6315 Flammability/ Flame Extension	A	The product and its components are not considered to be flammable.	483992-02
830.6316 Explodability	A	The product and its components are not explodable and do not have the capability to undergo an uncontrolled, rapid, violent chemical reaction resulting in a sudden increase in pressure.	483992-02
830.6317 Storage Stability	G	The product was reported to be stable for >1 year.	483992-02
830.6319 Miscibility ¹	A	The product is not an emulsified liquid and is not diluted with petroleum solvents.	483992-02
	A	The product is added to dilution water, or applied to process water in conjunction with sodium hypochlorite.	Label
830.6320 Corr o sion Characteristics	G		
830.6321 Dielectric Breakdown Voltage	Α	[Waived.]	483992-02
		The product is to be generated and fed into treatment water systems through a proper chemical feed skid only by a trained Kemira representative.	Label
830.7000 pH ²	A	pH 9.66 (Neat) pH 8.25 (1% w/w aqueous)	486904-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7050 UV/Visible Absorption	NA	[Not required for end-use products.]	
830.7100 Viscosity	A	1.731 (@20 °C), 1.190 (@40 °C) Centistokes	486904-01
830.7200 Melting Point/Melting Range	NA	[Not required for end-use products.]	
830.7220 Boiling Point/Boiling Range	NA	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	А	1.179 g/ml (@ 20 °C)	486904-01 And CSF
830.7370 Dissociation Constants in Water	NA	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NA	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NA	[Not required for end-use products.]	
830.7950 Vapor Pressure	NA	[Not required for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

^{*} Provide brief description, e.g., color - yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid ²If product is dispersible with water

Product Safety

October 6, 2011

VOLUME 1 of 2 Administrative Materials

Document Processing Desk Office of Pesticide Programs (7504P) Environmental Protection Agency One Potomac Yard 2777 S. Crystal Drive, Room S-4900 Arlington VA 22202

Attn: Velma Noble, PM 31

RE:

Data Transmittal Document

Product: EPA Reg. No. Fennosurf 586

Company:

9386-UO Kemira Chemicals, Inc.

Regulatory Action:

Supplementary submission in response to 75 day deficiency email from

Tracy Lantz dated 9/22/11

Dear Ms. Noble:

On behalf of Kemira Chemicals, Inc., I am submitting the Preliminary Analysis study in response to an email dated 9/22/11 from Tracy Lantz regarding deficiencies, for the product Fennosurf 586, EPA Reg. No. 9386-UO. We have enclosed three copies of each volume.

List of Submitted Documents:

Volume 1 of 2: Administrative Materials

- · Data Transmittal Document
- EPA form 8570-1
- Cover Letter

48637101

Volume 2 of 2: Fennosurf 586: Preliminary Analysis

If you have any questions regarding this submission, please contact me at 678-819-4566, or Coffeen.Snyder@Kemira.com.

Sincerely,

Colleen M. Snyder Product Safety Expert

Kemira Chemicals, Inc.

Colleen Sunder



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

December 12, 2011

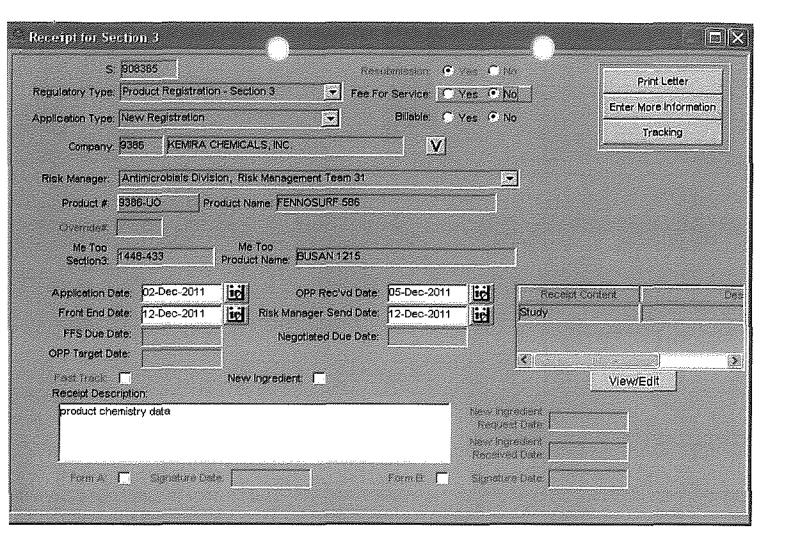
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

KEMIRA CHEMICALS, INC. 1000 PARKWOOD CIRCLE, SUITE 500 ATLANTA, GA 30339

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 05-DEC-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



file sy ('ool 9386 - UO

48690400



FENNSURF 586 Group B Product Chemistry Snyder Colleen

to:

Tracy Lantz, Earl Goad 12/02/2011 03:54 PM

Hide Details

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA, Earl Goad/DC/USEPA/US@EPA

2 Attachments





image001.png Kemira 32513Phys Chem.pdf

Tracy,

Please find attached the pH, density, viscosity study result Earl has requested. 4869

48690401

Earl,

Thank you for speaking with me yesterday. Feel free to call me should you find the need.

Have a great weekend!

Colleen M Snyder

Product Safety Expert, Biocides-North America, Global Tissue Specialties & Felt Cleaners

Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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300000

0 h 606636

file sy bol 9386 - UO





FENNSURF 586 Group B Product Chemistry Snyder Colleen

to:

Tracy Lantz, Earl Goad 12/02/2011 03:54 PM

Hide Details

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA, Earl Goad/DC/USEPA/US@EPA

2 Attachments





image001.png Kemira 32513Phys Chem.pdf

Tracy,

Please find attached the pH, density, viscosity study result Earl has requested.

48690401

Earl,

Thank you for speaking with me yesterday. Feel free to call me should you find the need.

Have a great weekend!

Colleen M Snyder

Product Safety Expert, Blocides-North America, Global Tissue Specialties & Felt Cleaners

Tel +678 819 4566 | Mobile +412-780-7913 | Colleen Snyder@kemira.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

October 13, 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

KEMIRA CHEMICALS, INC. 1000 PARKWOOD CIRCLE, SUITE 500 ATLANTA, GA 30339

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 06-OCT-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

DATA PACKAGE BEAN SHEET

Date: 20-Oct-2011
Page 1 of 2

Decision #: 445675 DP #: (394455)

PRIA

Parent DP #:

Submission #: 890858

E-Sub #:

* * * Registration Information * * * Registration: 9386-UO - FENNOSURF 586

Registration:	9386-UO - FENNOSU	IRF 586				
Company:	9386 - KEMIRA-CHEMICA	LS, INC.		·	-	
Risk Manager:	RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855					
Risk Manager Reviewer:	Tracy Lantz TLANTZ					
Sent Date:		Calculated Due Da	te: 23-Dec-2011	Edited	Due Date:	
Type of Registration:	Product Registration - Sect	lon 3				
Action Desc:	(A532) UNREGISTERED S	OURCE OF ACTIVE IN	GREDIENT;NEW F	PRODUCT;CITE-ALL DA	<u>A</u>	
Ingredients:	005601, Ammonium sulfate	a(7.59%)				
	* * * [Data Package In	formation *	* *		
Expedite:	◯ Yes ● No	Date Se	Date Sent: 26-Sep-2011		Due Back:	
DP Ingredient:	005601, Ammonium sulfate	<u> </u>				
DP Title:					м.	
CSF Included:		bel Included: O Yes (No Parer	nt DP #:		
Assigned To	<u>o</u>	Date In	Date Dut			
Organization: AD / P	SB	26-Sep-2011		Last Possible Science	Due Date:	23-Nov-2011
Team Name: CTT		26-Sep-2011		Science	Due Date:	09-Dec-2011
Reviewer Name: Middle	eton, Veronica			Sub Data Package	Due Date:	23-Dec-2011
Contractor Name: CSC		30-Sep-2011				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Karen: Please review product chemistry data including MRID 483992-01 and -02. This package is incomplete. We are still waiting for them to submit chemistry data on unregistered source of A.I. Please let us know if there are deficiencies with the information submitted thus far.

Product Safety

5-Oct-2011

FENNOSURF 586 (EPA REG. # 9386-UO)

Ms. Velma Noble Product Manager #31
Office of Pesticide Programs
US Environmental Protection Agency
Antimicrobial Division (7504P)
1200 Pennsylvania Avenue NW
Washington DC 20460

Courier:

Document Processing Desk (REGFEE)
Ms. Velma Noble Product Manager #31
Office of Pesticide Programs (7504P)
Room S-4900 One Potomac Yard-South Building
2777 South Crystal Drive
Arlington VA 22202-4501

VIA eMail

RE: Response to Deficiencies: Your cmail dated 22SEPT2011 75 day deficiency letter for 9386-UO

Dear Ms Noble:

In response to your email dated September 22, 2011 Kemira respectfully provides the included information that will satisfy the notated deficiency:

One (1) copy Final Report titled *Preliminary Analysis of Ammonia FENNOSURF* 586, US EPA PRODUCT PROPERTIES TEST GUIDELINES OPPTS 830.1700.

The Agency has requested data to validate Kemira Chemicals Inc claim of Substantially Similar product identity to support a Me-Too application. Kemira's application cites existing data provided to the Agency on both the Source Material and the End Use Product. The only remaining question is to supply data to confirm Kemira's unregistered source material (ammonia) is Substantially Similar to the cited products.

Kemira feels it may have created some confusion at the Agency around ammonium sulfate being used as an ingredient to generate the source material, ammonia. To help make this cleare a bref discussion of the formulation process follows.

Page 1 of 2



The Preliminary Analysis supplied here was conducted on five laboratory batches of Fennosurf 586. It shows that the arrival to aqueous ammonia is identical to that of the EPA registered source in Kemira's Selective Cite All application. Kemira is available at your convenience to discuss this chemistry further and would appreciate your forwarding the Preliminary Analysis on for review along with the application materials previously submitted.

Respectfully,

Colleen M Snyder Product Safety Expert

cc: Tracy Lantz - EPA

Dennis Edwards-EPA

Stanley H. Abramson, Partner-Arent Fox LLP

Collen M Snyder

Jeff Jones-Delta

Fw 75 day deficiency letter for 9 Product Safety

October 6, 2011

VOLUME 1 of 2 Administrative Materials

Document Processing Desk Office of Pesticide Programs (7504P) Environmental Protection Agency One Potomac Yard 2777 S. Crystal Drive, Room S-4900 Arlington VA 22202

Attn: Velma Noble, PM 31

RE:

Data Transmittat Document

Product:

Fennosurf 586

EPA Reg. No.

9386-UO

Company:

Kemira Chemicals, tnc.

Regulatory Action:

Supplementary submission in response to 75 day deficiency email from

Tracy Lantz dated 9/22/11

Dear Ms. Noble:

On behalf of Kemira Chemicals, Inc., I am submitting the Preliminary Analysis study in response to an email dated 9/22/11 from Tracy Lantz regarding deficiencies, for the product Fennosurf 586, EPA Reg. No. 9386-UO. We have enclosed three copies of each volume.

List of Submitted Documents:

Volume 1 of 2:

Administrative Materials

- · Data Transmittal Document
- EPA form 8570-1
- · Cover Letter

48637101

Volume 2 of 2: Fennosurf 586: Preliminary Analysis

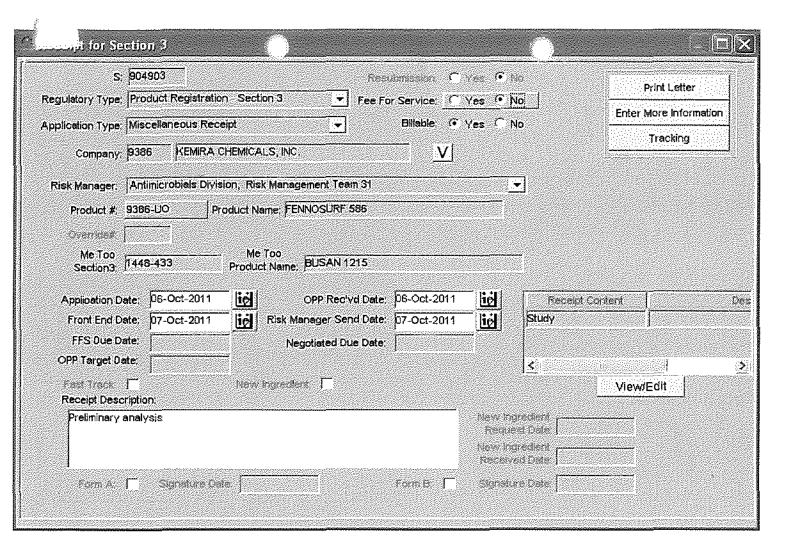
If you have any questions regarding this submission, please contact me at 678-819-4566, or Colleen.Snyder@Kemira.com.

Sincerely,

Colleen M. Snyder Product Safety Expert

Kemira Chemicals, Inc.

Colleen Sunder





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

October 13, 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

KEMIRA CHEMICALS, INC. 1000 PARKWOOD CIRCLE, SUITE 500 ATLANTA, GA 30339

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 06-OCT-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

FENNSURF 586 Group B Product Chemistry Snyder Colleen

to:

Tracy Lantz, Earl Goad 712/02/2011 03:54 PM

Hide Details

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA, Earl Goad/DC/USEPA/US@EPA

400 Keresa John MRD or 12/2/11

2 Attachments





image001.png Kemira 32513Phys Chem.pdf

Tracy,

Please find attached the pH, density, viscosity study result Earl has requested.

Earl,

Thank you for speaking with me yesterday. Feel free to call me should you find the need.

Have a great weekend!

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 Mobile +412-780-7913 Colleen.Snyder@kemira.com

Kemira Chemicais, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com www.waterfootprintkemira.com

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Kemira



Kemira Chemicals Inc - Record of Meeting October 25, 2011 (EPA REG# 9386-UO)

Snyder Colleen to: Dennis Edwards, Tracy Lantz

10/28/2011 01:41 PM

Velma Noble, Keegan Ken, Clark Michael, "Abramson, Stanley

Cc: (Abramson.Stanley@ArentFox.com)"

"angela.levin@troutmansanders.com", Perez Carolina

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Dennis Edwards/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA

Cc:

Velma Noble/DC/USEPA/US@EPA, Keegan Ken <Ken.Keegan@kemira.com>, Clark Michael <Michael.Clark@kemira.com>, "Abramson, Stanley (Abramson.Stanley@ArentFox.com)"

<Abramson.Stanley@ArentFox.com>, "angela.levin@troutmansanders.com"

Dennis and Tracy,

Thank you for taking our meeting on Tuesday, October 25, 2011; your contribution to clarify any outstanding data requirements is very much appreciated. We have summarized a few key points from our telephone conversation. Your review and inclusion of any clarifying comments is appreciated.

Record of Meeting October 25, 2011

Participants:

Mr. Dennis Edwards-EPA

Ms. Tracy Lantz-EPA

Mr. Ken Keegan-Kemira

Mr. Michael Clark-Kemira

Ms. Colleen 5nyder-Kemira

Mr. Stanley Abramson-Arent Fox

Ms. Angela Levin-Troutman Sanders

* Kemira clarified that it is Kemira's intent to follow the Buckman application, in which Ammonia is the active ingredient, for Kemira's Me-Too EUP registration (9386-UO) FENNOSURF 586. Ammonium Sulfate is a raw material used to generate the Ammonia. The Confidential Statement of Formula submitted by Kemira supports this clarification. Kemira's chemist, Mr. Michael Clark, described the

Ammonia. Mr. Edwards acknowledged this description and indicated that he would confirm this with the chemist.

- * Based on Kemira's clarification that its application is intended to follow Buckman's application, Mr. Edwards acknowledged that it is only fair to request of Kemira what was requested of Buckman in support of its application. As a result, Mr. Edwards agreed to go back and look at the chemistry data requested from Buckman. Once this has been completed, Mr. Edwards will get back in touch with Ms. Snyder to confirm what, if any, additional information is required to support the application.
- * In response to a request for a certificate of analysis on Ammonium Sulfate (technical grade, not

EUP), Kemira clarified that this has already been provided on August 25, 2011 as a supplemented packet of supporting information labeled "SUPPLEMENT TO ORIGINAL END USE PRODUCT REGISTRATION SUBMITTED FEBRUARY 17, 2011." Mr. Edwards agreed to go back and review what had been submitted.

We appreciate your recognition that this is a time sensitive matter and look forward to your response,

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

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RE: 75 day deficiency letter for 9386-UO

Snyder Colleen

to:

Tracy Lantz

10/21/2011 02:02 PM

Cc:

Velma Noble, Dennis Edwards, Keegan Ken, Clark Michael, Perez Carolina, "Abramson, Stanley (Abramson, Stanley @ArentFox.com)", "angela.levin@troutmansanders.com"

Hide Details

From: Snyder Colleen Sort List...

To: Tracy Lantz/DC/USEPA/US@EPA

Cc: Velma Noble/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Keegan Ken, Clark Michael, Perez Carolina, "Abramson, Stanley (Abramson, Stanley@ArentFox.com)",

"angela.levin@troutmansanders.com"

Hi Tracy,

This is an update to my previous email. Since Kemira will have several people on this call to fully capture and understand the outstanding data requirements: I thought I would initiate the conference call invite and provide the call in number.

At 4:30 PM EST on Tuesday, October 25, 2011 please call:

1-866-410-9106

Participant Code #

Have a great weekend,

Colleen M Snyder

Product Safety Expert, Biocides- North America, Globar Tissue Specialities & Peit Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

16: +0/6 618 4000 | WIDDIE +4 12-760-7810 | CONECTION OF WATER ALCOHO

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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Buckman: 1448-432

1448- 433

Commercial/financial information may be entitled to confidential treatment

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Kemira

----Original Message----From: Snyder Colleen

Sent: Friday, October 21, 2011 9:53 AM To: 'Lantz.Tracy@epamail.epa.gov' Cc: Noble.Velma@epamail.epa.gov

Subject: RE: 75 day deficiency letter for 9386-UO

Hi Tracy,

Tuesday at 4:30 PM works. Please ask Dennis Edwards to join. I will have a few people from Kemira on the call. Please forward the call-in number to me and will set it up on this end.

Have a great week end.

Colleen

----Original Message----

From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, October 20, 2011 5:41 PM

To: Snyder Colleen

Cc: Noble.Velma@epamail.epa.gov

Subject: RE: 75 day deficiency letter for 9386-UO

Heft you two voice mail messages today.

We would like to speak to you via conference call on Tuesday, 10/25 at

4:30 PM east coast time.

Please confirm that you will be available at this time and indicate the phone number we should call.

Thanks

[Embedded image moved to file: pic17253.jpg]

From: Snyder Colleen < Colleen. Snyder@kemira.com>

Tracy Lantz/DC/USEPA/U5@EPA To:

Cc: Jeff Jones <jjones@delta-ac.com>, Velma

Noble/DC/USEPA/US@EPA

Date: 10/07/2011 08:14 AM

Subject:

RE: 75 day deficiency letter for 9386-UO

Tracy,

If you have time in schedule today, I would like to have a telephone conversation.

file://C:\Documents and Settings\Tracy\Local Settings\Temp\notes35A6F9\~web4755.htm

Velma and I spoke 10/13
Velma where on 10/13
(confirm
this is correct date)

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

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----Original Message----

From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, October 06, 2011 6:05 PM

To: Snyder Colleen

Cc: Jeff Jones; VelmaNoble/DC/USEPA/US

Subject: Fw: 75 day deficiency letter for 9386-UO

Is the preliminary analysis the only study you intend to submit at this time? Are you still waiting for other chemistry studies to be completed?

Please also recall that as per the attached 75 day deficiency letter, you must reply with a proposed renegotiated due date of 120 days from the date your fix is received at front end processing. (Embedded image moved to file: pic10430.jpg)

---- Forwarded by Tracy Lantz/DC/USEPA/US on 10/06/2011 06:00 PM ----

From:

Tracy Lantz/DC/USEPA/US

To: Cc: Snyder Colleen <Colleen.Snyder@kemira.com> Velma Noble/DC/USEPA/US@EPA, Jeff Jones

<ijones@delta-ac.com>

Date:

10/0S/2011 05:28 PM

Subject:

RE: 7S day deficiency letter for 9386-UO

Please confirm that you have sent hard copies of both of these documents to front end processing so that this study will receive an MRID.

Once your study has passed the front end screening for 86-S and received an MRID I will be able to place the data into review with our chemists.

Thanks

(Embedded image moved to file: pic194S1.jpg)

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

Velma Noble/DC/USEPA/US@EPA, Jeff Jones

<jjones@delta-ac.com>, Dennis Edwards/DC/USEPA/US@EPA,
"Abramson, Stanley (Abramson.Stanley@ArentFox.com)"

<a href="mailto:, Keegan Ken

<Ken.Keegan@kemira.com>

Date:

10/05/2011 0S:19 PM

Subject:

RE: 75 day deficiency letter for 9386-UO

Hi Tracy,

I have attached the Preliminary Analysis conducted on the source material and covering letter to be further forwarded to those reviewing subject. Please let me know as soon as possible that you are in receipt and the deficiencies addressed in your previous emails have been fulfilled.

Respectfully submitted,

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile

+412-780-7913 Colleen.Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite S00, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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----Original Message-----

From: Lantz.Tracy@epamail.epa.gov (mailto:Lantz.Tracy@epamail.epa.gov)

Sent: Tuesday, September 27, 2011 4:46 PM

To: Snyder Colleen; Jeff Jones Cc: Noble.Velma@epamail.epa.gov

Subject: Fw: 7S day deficiency letter for 9386-UO

Please confirm that you received this message which was sent last week.

Thanks

(Embedded image moved to file: pic11320.jpg)

---- Forwarded by Tracy Lantz/DC/USEPA/US on 09/27/2011 04:45 PM ----

From:

Tracy Lantz/DC/USEPA/U5

To:

"'5nyder Colleen'"

<Colleen.Snyder@kemira.com>, "Jeff

Jones"

<jjones@delta-ac.com>

Cc:

Velma Noble/DC/USEPA/US@EPA, Dennis

Edwards/DC/USEPA/US@EPA

Date:

09/22/2011 05:52 PM

Subject:

7S day deficiency letter for 9386-UO

We have received the information you submitted at the end of August, 2011. This additional information still does not satisfy the deficiencies associated with the data requirements for the unregistered source of active ingredient. We have discussed your application with our Office of General Counsel. Please see the letter below for additional details.

You will receive a hard copy of this letter in the mail soon. Please reply indicating that you have received this message.

OPP Decision Number D44S675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject:

Fennosurf 586

EPA File Symbol:

9386-UO

Application Dated:

February 17, 2011

EPA Receipt Date:

February 22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on December 23, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. You are permitted

75 days to respond to the deficiencies listed below before the Agency withdraws your application. Therefore you must contact the Agency by December 8,

2011 to explain how you will address the deficiencies along with a mutually agreed upon renegotiated PRIA due date or receive a determination not to grant your application.

If, after 75 days from the date of this letter, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. This action would result in your submission being removed from the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and PRIA. Any subsequent submission relating to the application must be submitted as a new PRIA application and subject to fees.

Address the following deficiencies:

Chemistry Data on the Source Material

Your formulation does not utilize an EPA registered source of active ingredient. Therefore you must provide chemistry data on the unregistered technical source of active ingredient. We will use this information to make a determination as to whether or not your product is similar to other registered known sources of this active ingredient. Your application includes chemistry data on the formula you intend to register (7.59%), but not on the technical source

The chemistry data requirements are necessary as per the regulations at Part 158. This is true even when the assertion is made that the formulated product is identical to another cited product. Citing data on the Buckman products (EPA Reg. No. 1448-432 and 1448-433) will not satisfy the data requirements. The chemistry data in part serves the important function of verifying the information provided on the CSF. This function cannot be achieved by citing existing data on other registered products, however similar they are asserted to be.

Submit studies performed on the unregistered source of active ingredient to satisfy the Group A and B chemistry data requirements.

These deficiencies must be corrected before the Agency can proceed further with this application. You are urged to contact the Agency before December 8, 2011 and commit to a schedule to resolve the deficiencies including your proposed re-negotiated due date for this PRIA action.

You have the following three options.

1. Resolve the issue(s). You may resolve the issues identified in this letter by submitting a reply to the Agency by October 20, 2011 with information as how you plan to address the deficiencies. Please include your proposed re-negotiated PRIA due date and the date you expect to submit the fix at this

time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 120-days for Agency review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.

- 2. Withdraw the applications. Alternatively, you may notify us not later than October 20, 2011 that you are withdrawing your applications. As noted above, withdrawal concludes the Agency's review of your application. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.
- 3. Do nothing. If you do not respond to this letter by December 7, 2011 or if you do not wish to re-negotiate the PRIA deadline, the Agency will issue a determination not to grant your application. A determination not to grant your application would remove your application from the provisions of PRIA. Subsequent re-submissions would require a new PRIA application and fee. Because this determination is not a denial under section 3(c) (6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c) (6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing. If the request for a formal denial is not received 75 days from the date of this letter, the Agency will administratively withdraw the submission pursuant to 40 CFR 152.105.

Please respond to this letter by October 20,

2011 by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov , Velma Noble by telephone at (703)

308-6233 or by e-mail at Noble.velma@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

(Embedded image moved to file: pic07358.jpg) (attachment "9386-UO Cover Ltr Preliminary Analysis.pdf" deleted by Tracy Lantz/DC/U5EPA/US) (attachment "9386-UO Preliminary Analysis.pdf" deleted by Tracy Lantz/DC/USEPA/US)



Fw: 75 day deficiency letter for 9386-UO

Tracy Lantz to: Snyder Colleen

Cc: Velma Noble

10/12/2011 02:28 PM

I just called you again today and left messages at both of your phone numbers.

Please reply to Velma or myself as soon as possible.

We need confirmation of whether your data was sent to front end processing, will any additional data be submitted and you need to renegotiate the due date to allow time for Agency review of your new information.

(see my previous e-mail messages and letters dated July 14th and Sept 22nd)

Thanks

Tracy Lantz

Regulatory Team 31 **Antimicrobials Division**

Drag Lante

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

---- Forwarded by Tracy Lantz/DC/USEPA/US on 10/12/2011 02:25 PM -----

From:

Tracy Lantz/DC/USEPA/US

To:

Snyder Colleen < Colleen. Snyder@kemira.com>

Cc:

Velma Noble/DC/USEPA/US@EPA

Date:

10/11/2011 11:03 AM

Subject:

RE: 75 day deficiency letter for 9386-UO

Friday and Monday were my days off.

We just called you and left messages at both of your numbers.

Please return our call as soon as possible.

Thanks

Tracy Lantz

Regulatory Team 31 **Antimicrobials Division**

Draw Lante

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

Snyder Colleen

Tracy, if you have time in schedule today, I woul... 10/07/2011 08:14:26 AM

From:

Snyder Colleen <Colleen.Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

Jeff Jones <jjones@delta-ac.com>, Velma Noble/DC/USEPA/US@EPA

Date:

10/07/2011 08:14 AM

Subject:

RE: 75 day deficiency letter for 9386-UO

Tracy,

If you have time in schedule today, I would like to have a telephone conversation.

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners

Tel +678 819 4566 Mobile +412-780-7913 Colleen.Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

The content of this message is confidential and it may contain information protected by copyright.

If you have received this message in error, forwarding, copying, printing or other use of it is prohibited.

We request that you inform the sender of the error and then delete the message.

----Original Message----

From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, October 06, 2011 6:05 PM

To: Snyder Colleen

Cc: Jeff Jones; VelmaNoble/DC/USEPA/US

Subject: Fw: 75 day deficiency letter for 9386-UO

Is the preliminary analysis the only study you intend to submit at this time? Are you still waiting for other chemistry studies to be completed?

Please also recall that as per the attached 75 day deficiency letter, you must reply with a proposed renegotiated due date of 120 days from the date your fix is received at front end processing.

[Embedded image moved to file: picl0430.jpg]

---- Forwarded by Tracy Lantz/DC/USEPA/US on 10/06/2011 06:00 PM ----

From:

Tracy Lantz/DC/USEPA/US

To: Cc: Snyder Colleen <Colleen.Snyder@kemira.com>
Velma Noble/DC/USEPA/US@EPA, Jeff Jones

<jjones@delta-ac.com>

Date:

10/05/2011 05:28 PM

Subject:

RE: 75 day deficiency letter for 9386-UO

Please confirm that you have sent hard copies of both of these documents to front end processing so that this study will receive an MRID. Once your study has passed the front end screening for 86-5 and received an MRID I will be able to place the data into review with our chemists.

Thanks

(Embedded image moved to file: picl9451.jpg)

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

Velma Noble/DC/USEPA/US@EPA, Jeff Jones

<jjones@delta-ac.com>, Dennis Edwards/DC/USEPA/US@EPA,
"Abramson, Stanley (Abramson.Stanley@ArentFox.com)"

<Abramson.Stanley@ArentFox.com>, Keegan Ken

<Ken.Keegan@kemira.com>

Date:

10/05/2011 05:19 PM

Subject:

RE: 75 day deficiency letter for 9386-UO

Hi Tracy,

I have attached the Preliminary Analysis conducted on the source material and covering letter to be further forwarded to those reviewing subject. Please let me know as soon as possible that you are in receipt and the deficiencies addressed in your previous emails have been fulfilled.

Respectfully submitted,

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners Tel +678 819 4566 | Mobile +412-780-7913 | Colleen.Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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Sent: Tuesday, September 27, 2011 4:46 PM

To: Snyder Colleen; Jeff Jones Cc: Noble.Velma@epamail.epa.gov

Subject: Fw: 75 day deficiency letter for 9386-UO

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(Embedded image moved to file: pic11320.jpg)

---- Forwarded by Tracy Lantz/DC/USEPA/US on 09/27/2011 04:45 PM -----

From: Tracy Lantz/DC/USEPA/US

To: "'Snyder Colleen'" <Colleen.Snyder@kemira.com>,

"Jeff Jones"

<jjones@delta-ac.com>

Cc: Velma Noble/DC/USEPA/US@EPA, Dennis

Edwards/DC/USEPA/US@EPA

Date: 09/22/2011 05:52 PM

Subject: 75 day deficiency letter for 9386-UO

We have received the information you submitted at the end of August, 2011. This additional information still does not satisfy the deficiencies associated with the data requirements for the unregistered source of active ingredient. We have discussed your application with our Office of General Counsel. Please see the letter below for additional details.

You will receive a hard copy of this letter in the mail soon. Please reply indicating that you have received this message.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject:

Fennosurf 586

EPA File Symbol: 9386-UO Application Dated: February

17, 2011

EPA Receipt Date: February

22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on December 23, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. You are permitted 75 days to respond to the deficiencies listed below before the Agency withdraws your application. Therefore you must contact the Agency by December 8,

2011 to explain how you will address the deficiencies along with a mutually agreed upon renegotiated PRIA due date or receive a determination not to grant your application.

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Address the following deficiencies:

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registered source

of active ingredient. Therefore you must provide chemistry data on the unregistered technical source of active ingredient. We will use this information to make a determination as to whether or not your product is similar to other registered known sources of this active ingredient. Your application includes chemistry data on the formula you intend to register (7.59%), but not on the technical source

The chemistry data requirements are necessary

as per the

regulations at Part 158. This is true even when the assertion is made that the formulated product is identical to another cited product. Citing data on the Buckman products (EPA Reg. No. 1448-432 and 1448-433) will not satisfy the data requirements. The chemistry data in part serves the important function of verifying the information provided on the CSF. This function cannot be achieved by citing existing data on other registered products, however similar they are asserted to be.

Submit studies performed on the unregistered

source of

active ingredient to satisfy the Group A and B chemistry data requirements.

These deficiencies must be corrected before the Agency can proceed further with this application. You are urged to contact the Agency before December 8, 2011 and commit to a schedule to resolve the deficiencies including your proposed re-negotiated due date for this PRIA action.

You have the following three options.

- 1. Resolve the issue(s). You may resolve the issues identified in this letter by submitting a reply to the Agency by October 20, 2011 with information as how you plan to address the deficiencies. Please include your proposed re-negotiated PRIA due date and the date you expect to submit the fix at this time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 120-days for Agency review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.
- 2. Withdraw the applications. Alternatively, you may notify us not later than October 20, 2011 that you are withdrawing your applications. As noted above, withdrawal concludes the Agency's review of your application. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.
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RE: 75 day deficiency letter for 9386-UO

Tracy Lantz to: Snyder Colleen Cc: Velma Noble, Jeff Jones

10/05/201 t 05:28 PM

will be and chem.

Please confirm that you have sent hard copies of both of these documents to front end processing so that this study will receive an MRID.

Once your study has passed the front end screening for 86-5 and received an MRID I will be able to place the data into review with our chemists.

Thanks

Tracy Lantz

Regulatory Team 31
Antimicrobials Division

Drag Lants

U.S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

Snyder Colleen Hi Tracy, I have attached the Preliminary Analys...

10/05/2011 05:19:04 PM

From: Snyder Colleen <Colleen.Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA

Cc: Veima Noble/DC/USEPA/US@EPA, Jeff Jones <ijjones@delta-ac.com>, Dennis

Edwards/DC/USEPA/US@EPA, "Abramson, Stanley (Abramson.Stanley@ArentFox.com)"

<a href="mailto: Abramson.Stantey@ArentFox.com, Keegan Ken Keegan@kemira.com

Date: 10/05/2011 05:19 PM

Subject: RE: 75 day deficiency letter for 9386-UO

Hi Tracy,

I have attached the Preliminary Analysis conducted on the source material and covering letter to be further forwarded to those reviewing subject. Please let me know as soon as possible that you are in receipt and the deficiencies addressed in your previous emails have been fulfilled.

Respectfully submitted,

Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners

Tel +678 819 4566 Mobile +412-780-7913 Colleen. Snyder@kemira.com

Kemira Chemicals, Inc 1000 Parkwood Circle, Suite 500, Atlanta, GA 30339 USA www.kemira.com | www.waterfootprintkemira.com

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RE: 75 day deficiency letter for 9386-UO

Snyder Colleen to: Tracy Lantz

Nelma Noble, Jeff Jones

, Dennis Edwards, "Abramson,

10/05/2011 05:19 PM

Stanley (Abramson.Stanley@ArentFox.com)", Keegan Ken

History:

This message has been replied to.

2 attachments





9386-UO Cover Ltr Preliminary Analysis.pdf9386-UO Preliminary Analysis.pdf

Hi Tracy,

I have attached the Preliminary Analysis conducted on the source material and covering letter to be further forwarded to those reviewing subject. Please let me know as soon as possible that you are in receipt and the deficiencies addressed in your previous emails have been fulfilled.

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Colleen M Snyder

Product Safety Expert, Biocides- North America, Global Tissue Specialties & Felt Cleaners

Tel +678 819 4566 Mobile +412-780-7913 Colleen.Snyder@kemira.com

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Subject: Fw: 75 day deficiency letter for 9386-UO

Please confirm that you received this message which was sent last week.

Thanks

(Embedded image moved to file: picll320.jpg)

---- Forwarded by Tracy Lantz/DC/USEPA/US on 09/27/2011 04:45 PM -----

From: Tracy Lantz/DC/USEPA/US

To: "'Snyder Colleen'" < Colleen.Snyder@kemira.com>, "Jeff Jones"

<jjones@delta-ac.com>

Cc: Velma Noble/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA

Date: 09/22/2011 05:52 PM

Subject: 75 day deficiency letter for 9386-UO

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OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject: Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on December 23, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. You are permitted 75 days to respond to the deficiencies listed below before the Agency withdraws your application. Therefore you must contact the Agency by December 8, 2011 to explain how you will address the deficiencies along with a mutually agreed upon renegotiated PRIA due date or receive a determination not to grant your application.

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The chemistry data requirements are necessary as per the regulations at Part 158. This is true even when the assertion is made that the formulated product is identical to another cited product. Citing data on the Buckman products (EPA Reg. No. 1448-432 and 1448-433) will not satisfy the data requirements. The chemistry data in part serves the important function of verifying the information provided on the CSF. This function cannot be achieved by citing existing data on other registered products, however similar they are asserted to be.

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5-Oct-2011

FENNOSURF 586 (EPA REG. # 9386-UO)

Ms. Velma Noble Product Manager #31
Office of Pesticide Programs
US Environmental Protection Agency
Antimicrobial Division (7504P)
1200 Pennsylvania Avenue NW
Washington DC 20460

Courier:

Document Processing Desk (REGFEE)

Ms. Velma Noble Product Manager #31

Office of Pesticide Programs (7504P)

Room S-4900 One Potomac Yard-South Building

2777 South Crystal Drive

Arlington VA 22202-4501

VIA eMail

RE: Response to Deficiencies: Your email dated 22SEPT2011 75 day deficiency letter for 9386-UO

Dear Ms Noble:

In response to your email dated September 22, 2011 Kemira respectfully provides the included information that will satisfy the notated deficiency:

One (1) copy Final Report titled *Preliminary Analysis of Ammonia FENNOSURF* 586, US EPA PRODUCT PROPERTIES TEST GUIDELINES OPPTS 830.1700.

The Agency has requested data to validate Kemira Chemicals Inc claim of Substantially Similar product identity to support a Me-Too application. Kemira's application cites existing data provided to the Agency on both the Source Material and the End Use Product. The only remaining question is to supply data to confirm Kemira's unregistered source material (ammonia) is Substantially Similar to the cited products.

Kemira feels it may have created some confusion at the Agency around ammonium sulfate being used as an ingredient to generate the source material, ammonia. To help make this clearer a brief discussion of the formulation process follows.



The Preliminary Analysis supplied here was conducted on five laboratory batches of Fennosurf 586. It shows that the arrival to aqueous ammonia is identical to that of the EPA registered source in Kemira's Selective Cite All application. Kemira is available at your convenience to discuss this chemistry further and would appreciate your forwarding the Preliminary Analysis on for review along with the application materials previously submitted.

Respectfully,

Colleen M Snyder

Product Safety Expert

cc: Tracy Lantz - EPA

Dennis Edwards-EPA

Stanley H. Abramson, Partner-Arent Fox LLP

Collen M Snyder

Jeff Jones-Delta



Fw 75 day deficiency letter for 9

มทั่งED STATES ENVIRONMENTAL PROTECนเป**ก AGENCY**

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject:

Fennosurf 586

EPA File Symbol: 9386-UO

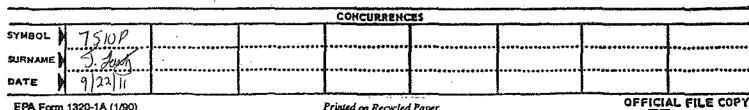
Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

SEP 2 2 2011

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EPA Form 1320-1A (1/90)

Printed on Recycled Paper

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Address the following deficiencies:

Chemistry Data on the Source Material

Your formulation does not utilize an EPA registered source of active ingredient. Therefore you must provide chemistry data on the unregistered technical source of active ingredient. We will use this information to make a determination as to whether or not your product is similar to other registered known sources of this active ingredient. Your application includes chemistry data on the formula you intend to register (7.59%), but not on the technical source

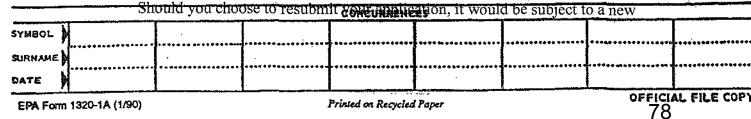
The chemistry data requirements are necessary as per the regulations at Part 158. This is true even when the assertion is made that the formulated product is identical to another cited product. Citing data on the Buckman products (EPA Reg. No. 1448-432 and 1448-433) will not satisfy the data requirements. The chemistry data in part serves the important function of verifying the information provided on the CSF. This function cannot be achieved by citing existing data on other registered products, however similar they are asserted to be.

Submit studies performed on the unregistered source of active ingredient to satisfy the Group A and B chemistry data requirements.

These deficiencies must be corrected before the Agency can proceed further with this application. You are urged to contact the Agency before December 8, 2011 and commit to a schedule to resolve the deficiencies including your proposed re-negotiated due date for this PRIA action.

You have the following three options.

- 1. Resolve the issue(s). You may resolve the issues identified in this letter by submitting a reply to the Agency by October 20, 2011 with information as how you plan to address the deficiencies. Please include your proposed renegotiated PRIA due date and the date you expect to submit the fix at this time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 120-days for Agency review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.
- 2. Withdraw the applications. Alternatively, you may notify us not later than October 20, 2011 that you are withdrawing your applications. As noted above, withdrawal concludes the Agency's review of your application.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

deadline for making a determination on your application and a new registration service fee.

3. Do nothing. If you do not respond to this letter by December 7, 2011 or if you do not wish to re-negotiate the PRIA deadline, the Agency will issue a determination not to grant your application. A determination not to grant your application would remove your application from the provisions of PRIA. Subsequent re-submissions would require a new PRIA application and fee. Because this determination is not a denial under section 3(c) (6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c) (6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing. If the request for a formal denial is not received 75 days from the date of this letter, the Agency will administratively withdraw the submission pursuant to 40 CFR 152.105.

Please respond to this letter by October 20, 2011 by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov, Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

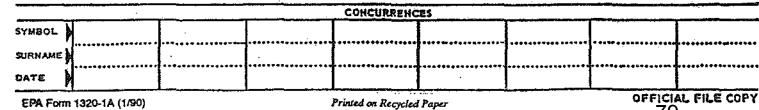
Sincerely,

Velma Noble

Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P)

7510P: T.Lantz:9/19/11 9386-UO 2nd letter more than 75 days





75 day deficiency letter for 9386-UO

Tracy Lantz to: 'Snyder Colleen', Jeff Jones

Cc: Velma Noble, Dennis Edwards

09/22/201 t 05:52 PM

We have received the information you submitted at the end of August, 2011. This additional information still does not satisfy the deficiencies associated with the data requirements for the unregistered source of active ingredient. We have discussed your application with our Office of General Counsel. Please see the letter below for additional details.

You will receive a hard copy of this letter in the mail soon. Please reply indicating that you have received this message.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject:

Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on December 23, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. You are permitted 75 days to respond to the deficiencies listed below before the Agency withdraws your application. Therefore you must contact the Agency by December 8, 2011 to explain how you will address the deficiencies along with a mutually agreed upon renegotiated PRIA due date or receive a determination not to grant your application.

If, after 75 days from the date of this letter, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. This action would result in your submission being removed from the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and PRIA. Any subsequent submission relating to the application must be submitted as a new PRIA application and subject to fees.

Address the following deficiencies:

Chemistry Data on the Source Material

Your formulation does not utilize an EPA registered source of active ingredient. Therefore you must provide chemistry data on the unregistered technical source of active ingredient. We will use this information to make a determination as to whether or not your product is similar to other registered known sources of this active ingredient. Your application includes chemistry data on the formula you intend to register (7.59%), but not on the technical source

The chemistry data requirements are necessary as per the regulations at Part 158. This is true even when the assertion is made that the formulated product is identical to another cited product. Citing data on the Buckman products (EPA Reg. No. 1448-432 and 1448-433) will not satisfy the data requirements. The chemistry data in part serves the important function of verifying the information provided on the CSF. This function cannot be achieved by citing existing data on other registered products, however similar they are asserted to be.

Submit studies performed on the unregistered source of active ingredient to satisfy the Group A and B chemistry data requirements.

These deficiencies must be corrected before the Agency can proceed further with this application. You are urged to contact the Agency before December 8, 2011 and commit to a schedule to resolve the deficiencies including your proposed re-negotiated due date for this PRIA action.

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- 1. Resolve the issue(s). You may resolve the issues identified in this letter by submitting a reply to the Agency by October 20, 2011 with information as how you plan to address the deficiencies. Please include your proposed re-negotiated PRIA due date and the date you expect to submit the fix at this time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 120-days for Agency review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.
- 2. Withdraw the applications. Alternatively, you may notify us not later than October 20, 2011 that you are withdrawing your applications. As noted above, withdrawal concludes the Agency's review of your application. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.
- 3. Do nothing. If you do not respond to this letter by December 7, 2011 or if you do

not wish to re-negotiate the PRIA deadline, the Agency will issue a determination not to grant your application. A determination not to grant your application would remove your application from the provisions of PRIA. Subsequent re-submissions would require a new PRIA application and fee. Because this determination is not a denial under section 3(c) (6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c) (6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing. If the request for a formal denial is not received 75 days from the date of this letter, the Agency will administratively withdraw the submission pursuant to 40 CFR 152.105.

Please respond to this letter by **October 20, 2011** by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov, Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

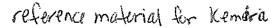
Tracy Lantz

Regulatory Team 31
Antimicrobials Division

Dray Lasts

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481





citation of product chemistry data Mark Dyner to: Dennis Edwards, Tracy Lantz

09/09/201 t 04:06 PM

as discussed.

Mark Dyner EPA Office of General Counsel

---- Forwarded by Mark Dyner/DC/USEPA/US on 09/09/20t1 04:04 PM ----

From:

Mark Dyner/DC/USEPA/US

To:

"Lawrence A. Miller" < lmiller@biologicconsulting.com>

Cc:

jmiller@biologicconsulting.com, Richard Gebken/DC/USEPA/US@EPA, Linda

Deluise/DC/USEPA/US@EPA

Date:

01/25/2011 12:35 PM

Subject:

RE: I Have a Question

Larry,

Linda, Richard & I met recently to discuss your question. While we agreed that analytical methods can be cited, the remaining product chemistry data requirements are necessary requirements for discrete formulated (as opposed to repackaged) products. The regulations at Part 158 make clear that these are product-specific requirements for formulated end-use products, such as Precision Control Technologies' product. This is true even when the assertion is made that the formulated product is identical to another cited product. The chemistry data in part serves the important function of verifying the formula. Information provided on the CSF of the formulated product. This function cannot be achieved by citing to existing data on other registered products, however similar they are asserted to be. If your client is not interested in conducting these studies, you may wish to pursue a repack registration (or multiple repack registrations) and claim the formulators' exemption for all required data, or, alternatively, perhaps you could seek a supplemental distributorship(s) for an existing registration, rather than a separate registration for a new formulated product. But that is your decision to make, obviously. In any case, if you're dissatisfied with this answer, you are of course free to request a meeting with OPP management to raise your concerns.

Regards,

Mark

Mark Dyner EPA Office of General Counsel (202) 564-1754

"Lawrence A. Miller"

Thanks Mark, Best Regards,

01/03/2011 01:15:47 PM

From:

"Lawrence A. Miller" < Imiller@biologicconsulting.com>

To: Cc: Mark Dyner/DC/USEPA/US@EPA <jmiller@biologicconsulting.com>

Date:

01/03/2011 01:15 PM

Subject:

RE: I Have a Question

Thanks Mark. Best Regards, Larry -Lawrence A. Miller BIOLOGIC, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 Tel: (203) 740-1200 Fax: (203) 740-1220 Email: lmiller@biologicconsulting.com CONFIDENTIALITY STATEMENT: This electronic message contains information that may be confidential or privileged. The information is intended solely for the use of the individual(s) or entity(ies) named above. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this email in error, please notify us immediately by telephone at 203-740-1200 or by email reply and delete this message. Thank you. ----Original Message----From: dyner.mark@epamail.epa.gov [mailto:dyner.mark@epamail.epa.gov) Sent: Monday, January 03, 2011 1:14 PM To: Lawrence A. Miller Cc: jmiller@biologicconsulting.com Subject: Re: I Have a Question Hey Larry, Hope the new year finds you well. As to your question, I'm going to touch base with Linda and Richard Gebken this week and then we'll try to get back with you as soon as possible thereafter. Mark Mark Dyner EPA Office of General Counsel |---> | From: ______ |"Lawrence A. Miller" < lmiller@biologicconsulting.com> 1 To: |---->

>		
1	Mark Dyner/DC/USEPA/US@EPA	
i -	Cc:	· · · · · · · · · · · · · · · · · · ·
	<pre> < <jmiller@biologicconsulting.com></jmiller@biologicconsulting.com></pre>	
-	Date:	
	12/30/2010 12:09 PM	
- - -		
	I Have a Question	

Hi Mark:

I have a question with regard to data citation. We submitted an application on behalf of Precision Control Technologies, Inc. for a mosquito ULV formulation containing permethrin and piperonyl butoxide as its active ingredients. This formulation is "identical" in its composition to a formulation that is currently registered by

Precision Control Technologies chose to cite the product chemistry studies Part A and B that was originally submitted by with an offer to pay for the use of their data.

Linda DeLuise sent us a letter indicating that the application is deficient because; (a.) the applicant cannot cite product chemistry data, and; (b.) labeling language must be corrected in accordance with the permethrin and piperonyl butoxide REDs (see attached .pdf file).

The labeling language can easily be corrected and is not an issue for us, however, we do not believe that there is anything in the regulations that prevent the applicant from citing to another registrant's data (e.g. since the product compositions are identical, it is a reasonable assumption the product chemistry studies are also identical). Although you may not remember, you and I had a similar discussion some years ago and I recall that you indicated there was nothing in the statute that would prevent an applicant from citing another company's product chemistry data. Can you please clarify this for me?

Many thanks, and wishing you a Healthy/Happy/Prosperous New Year.

Best Regards,

Larry -

Lawrence A. Miller BIOLOGIC, Inc. 115 Obtuse Hill Road Brookfield, CT 06804

Tel: (203) 740-1200 Fax: (203) 740-1220

Email: lmiller@biologicconsulting.com

CONFIDENTIALITY STATEMENT: This electronic message contains information that may be confidential or privileged. The information is intended solely for the use of the individual(s) or entity(ies) named above. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this email in error, please notify us immediately by telephone at 203-740-1200 or by email reply and delete this message. Thank you.

[attachment "OneTouch Dec 30, 2010 (1).PDF" deleted by Mark Dyner/DC/USEPA/US]

Notes:

9/9/11

Conference call Mark Dyner, Demis Edwards

Privileged attorney-client communication

Tray Lontz



9386-UO FENNOSURF 586 Snyder Colleen

to:

Tracy Lantz

08/26/2011 05:34 PM

Cc:

Dennis Edwards, Velma Noble, Keegan Ken, Jeff Jones

Hide Details

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA

Cc: Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Keegan Ken <Ken.Keegan@kemira.com>, Jeff Jones <jjones@delta-ac.com>



History: This message has been forwarded.

4 Attachments





FENNOSURF 586 Admin Vol I.pdf FENNOSURF 586 Group A Confidential Vol II.pdf





FENNOSURF 586 Group A Non-Confidential Vol II.pdf FENNOSURF 586 Group B Vol III.pdf

Hi Traci,

As per our meeting on Monday, August 22, 2011, I am sending you the Product Chemistry citation for the source material that will support our pesticide application for FENNOSURF S86. The emails attachments are labeled in four volumes. The application presentation is that of our original application dated February 17, 2011 and the supplementary Data Matrix for the source material.

This email will fulfill Kemira's commitment to present EPA our fix by August 28, 2011 and therefore, will not require an additional extension to review the Product Chemistry as we have fully cited Buckman's data by way of Selective Cite All Data Matrix.

We are all hoping that you stay safe during the storm.

Colleen M Snyder
Product Safety Expert-Biocides, Tissue Specialties
North America

WE'VE MOVED!

Kemira Chemicais Inc 1000 Parkwood Circle Suile 500 Allanta, GA 30339 USA Phone: +578 819 4555 Fax: +678 819 4625 email: Colieen,Snyder@Kemira.com www.kemira.com



PRINT THESE ASAP AND SEND TO FRONT END PROCESSING FOR MRID Fw: 9386-UO FENNOSURF 586

Tracy Lantz to: Tracy Lantz

09/07/2011 08:03 PM

Is this really group A & B chemistry data? Were they supposed to sent this 10 front end? Is this really the fix?

Tracy Lantz

Regulatory Team 31
Antimicrobials Division

Jracy Lag

U.S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

---- Forwarded by Tracy Lantz/DC/USEPA/US on 09/07/2011 08:00 PM ----

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Keegan Ken

<Ken.Keegan@kemira.com>, Jeff Jones <jjones@delta-ac.com>

Date:

08/26/2011 05:34 PM

Subject:

9386-UO FENNOSURF 586

Hi Traci,

As per our meeting on Monday, August 22, 2011, I am sending you the Product Chemistry citation for the source material that will support our pesticide application for FENNOSURF 586. The emails attachments are labeled in four volumes. The application presentation is that of our original application dated February 17, 2011 and the supplementary Data Matrix for the source material.

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We are all hoping that you stay safe during the storm.

Colleen M Snyder
Product Safety Expert-Biocides, Tissue Specialties
North America

WE'VE MOVED!

Kemira Chemicals Inc 1000 Parkwood Circle Suite 500 Atlanta, GA 30339 USA Phone: +678 819 4566 Fax: +678 819 4625 email: <u>Colleen.Snyder@Kemira.com</u> <u>www.kemira.com</u>



FENNOSURF 586 Admin Vol I.pdf FENNOSURF 586 Group A. Confidential Vol II.pdf

FENNOSURF 586 Group A Non-Confidential Vol II.pdf FENNOSURF 586 Group 8 Vol III.pdf

8/25/11 all updated info attached (although she did not put new dates on this information)

SUPPLEMENT TO ORIGINAL END USE PRODUCT REGISTRATION SUBMITTED February 17, 2011.

EPA REG # 9386-UO MRID NUMBERS GRANTED

GROUP A PRODUCT CHEMISTRY MRID # 483992-01 GROUP B PRODUCT CHEMISTRY MRID # 483992-02

Inclusion of:

- DATA MATRIX ON SOURCE MATERIAL.
- REVISED END USE PRODUCT LABEL.

MATERIALS HAVE BEEN UPDATED TO REFLECT COMPANY ADDRESS CHANGE, EPA REGISTRATION ID (9386-UO) AND AQUEOUS AMMONIA SOLUTION REFERENCES; AS DISCUSSED IN OUR AUGUST 22, 2011 MEETING. ALL ELSE HAS REMAINED AS PREVIOUSLY SUBMITTED. Ms. Velma Noble Product Manager #31
Office of Pesticide Programs
US Environmental Protection Agency
Antimicrobial Division (7504P)
1200 Pennsylvania Avenue NW
Washington DC 20460

Courier:

Document Processing Desk (REGFEE)

Ms. Velma Noble Product Manager #31

Office of Pesticide Programs (7504P)

Room S-4900 One Potomac Yard-South Building

2777 South Crystal Drive

Arlington VA 22202-4501

Package to include:

Vol I

- Transmittal Page
- Cover Letter
- One (1) Copy: Application for Registration EPA Form 8570-1
- * Two (2) copies: Confidential Statement of Formula
- One (1) Copy: Confidential Statement of Formula for an alternate formulation
- One (1) Copy: Data Matrix-End Use Product Specific
- One (1) Copy: Data Matrix-Source Material
 - Citation with Respect to Data
 - o Data Submitters List
- One (1) Copy: Citation with Respect to Data (REVISED TO INCLUDE MRID NUMBERS GRANTED FEBRUARY 22, 2011)
 - o Data Submitters List
- Five (5) copies: Draft Product Label

Vol II Product Chemistry Group A Non-Confidential (MRID # 483992-01)

Vol II Product Chemistry Group A Confidential Appendix

Vol II Product Chemistry Group B (MRID # 483992-02)

TRANSMITTAL PAGE

Submitter:	1000 Parkwo	Kemira Chemicals, Inc. 1000 Parkwood Circle Atlanta, GA 30339	
Regulatory Action:		nbol No. 9386-UO) Product Registration (PRIA-A532)	
Transmittal date:	Transmittal date: February 17, 2011		
List of submitted studies:			
• Volume I. Administrative Materials (Cover letter, Forms, Labels, Waivers)			
MRID#			
Volume II. Product Chemistry Group A Public			
MRID#	MRID#(MRID # 483992-01)		
Volume II. Product Chemistry Group A CONFIDENTIAL ATTACHMENT			
MRID#			
Volume II Product Chemistry Group B Public			
MRID#		(MRID # 483992-02)	
Company Official:	Colleen M Snyder	Collen M Snyder (Signature)	
Company Name:	Kemira Chemicals Inc		
Company contact:	Colleen M Snyder	678-819-4566	

address chemistry on AI (tech)	
tox data	
eco dasa	
Ken Kegan paper-group in N. America	
Colleen Snyder	
Je & Jones Deta Analytical	······································
Dennis	
Tracy	
Eorl	
Najn	
Chris	

Dennis - they are an unregistered source - they owe us

a chemistry package

Chois - had date on constant source technical - A+B

Chris - red data on unregistered source technical - A+B
95

entitled to confidential treatment entitled to confidential treatment* Dennis - darity label as ammonia - Same as they became concerned in Dec. when one sent letter to Natice Colleen- this product is not being sold or marketed at this time Must be done fix will be 60 days from now - they must talk to the supplier to see it they *Product ingredient source information may be Trang - we need another 120 day for review beyond *Manufacturing process information may be the 60 day fix. Dennis - they can't much the fix doto we need a complete fix *Internal we work review it piece meal Calleer interium report on 5 batch analysis by weeks end we dents need this -> only send in a a Najm - titration method is not very sensitive Earl - we would look at an excelerated Storage studies storage studies Dennis - condition of registration - Submit Dennis possible we could review faster than the additional 120 days. Collegen - They are loosing the competitive edge + Sales at

this time.

96

	Dennis - we work look at until we have a complete chemistry
	padrage.
	Collegn - their fix will be here in ~60 days ->
	send label this week + data comp - waiting
	for 5 bath apply alaysis
	Data coup - tox for end use - cite Buckeran
	they need to go cite all / one or literature
	We need whese forms - data matrix + certification up respect to citation of data
	Demis - propose new renegotration when the fix actually arrives 60 days from now.
	Marty nore likely to sign it she nows the fix is here.
-	Note on my & calendar for 10/10/11 watchfor fix
	No mention of whether they had been selling the products.
··············	

Internal deliberative information?



Re: Fennosurf 586; EPA File Symbol 9386-UO

Tracy Lantz to: Jeff Jones

Cc: "Snyder Colleen", Dennis Edwards, "Keegan Ken", Velma Noble

08/11/2011 06:04 PM

Thanks for your message.

The earliest we can meet with you is on Monday, August 22nd at 10 AM. Please reply with an indication of whether you can meet at this time.

The other company that registered this active ingredient provided group A chemistry data. You need to provide this data for your product as well.

Regarding the generic data requirements you would likely need to use the cite all method of support.

The 21 day screen of an application is a check to determine if the appropriate forms have been submitted. It does not address whether or not individual data requirements have been met.

Tracy Lantz

Regulatory Team 31
Antimicrobials Division

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

"Jeff Jones"

Tracy

08/11/2011 05:29:21 PM

From:

"Jeff Jones" <jjones@delta-ac.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

Dennis Edwards/DC/USEPA/US@EPA, Veima Noble/DC/USEPA/US@EPA, "Snyder Colleen"

<Colleen.Snyder@kemira.com>, "'Keegan Ken'" <Ken.Keegan@kemira.com>

Date:

08/11/2011 05:29 PM

Subject:

Fennosurf 586; EPA File Symbol 9386-UO

Tracy:

Following up on our earlier request for a meeting to discuss the deficiencies identified in your email of July 14, I am supplying the attached background materials. May we schedule the meeting on Tuesday, Wednesday or Thursday next week?

In its resubmission due on August 28th, Kemira proposes to address product chemistry requirements pertaining to its source of active ingredient using the certificates of analysis and data to address preliminary analysis requirements.

Physical and chemical properties requirements will be addressed from public literature.

I am sending the following attachments which may assist you when gathering the correct and appropriate EPA resources for our meeting:

8/17/11 ap Premeeting Chris Earl Naiya Karen H.

Tracy

Certificates of analysis for 5 samples of Kemira's source material

Internal deliberative information

Chronology of Kemira's initial application for registration of Fennosurf 586

The other generic data requirements will be addressed by either citing public literature, EPA assessments of ammonia, or previously submitted data with appropriate offers to pay compensation.

Kemira has constructed the chronology to try to clarify how its application passed the 21-day screening process and yet, no product chemistry review was conducted on the ostensibly "complete" package. We'd also like to understand why we were not informed of later deficiency finding until approximately 3 weeks prior to the PRIA due date. The appearance is that the product chemistry "deficiency" was bolstered by two other relatively minor deficiencies, a simple label fix and a possible exclusive issue, which turned out to be no issue at all.

Thanks for your consideration.

Sincerely,

Jeff Jones





CHRONOLOGY

Fennosurf 586 Initial Application for Registration 11 August 2011

17 February 2011	Kemira submits application
22 February 2011	EPA acknowledges receipt
28 February 2011	Kemira receives email from EPA classifying application as PR1A category 532 and requesting additional fee of \$2,977
7 March 2011	Kemira receives preliminary completeness check letter dated 2 March
15 March 2011	End of 21-day screening process (based on Feb. 22 receipt date)
5 April 2011	End of 21-day screening process (based on extension for payment of additional fee)
14 July 2011	EPA notifies Kemira of three deficiencies by email
18-22 July 2011	Tracy Lantz on leave
26 July 2011	Kemira receives EPA deficiency letter dated 14 July 2011 and postmarked 22 July 2011
5 August 2011	PRIA due date



Re: FW: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills 🗈

Tracy Lantz to: Jeff Jones

08/04/2011 05:00 PM

Cc: "Snyder Colleen", Dennis Edwards, Velma Noble

Thanks for your reply. Prior to the Agency participating in a meeting with you, we will have an internal meeting to discuss your proposal and to prepare to address your concerns.

In order to have the pre-meeting, we need your additional background materials so that the individual meeting members will have the opportunity to familiarize themseives with the information and hold a productive pre-meeting.

Thus I am unable to schedule either meeting until I have your additional background materials. Once I receive this information I will be able to determine who should attend each meeting and work to schedule both meetings. Please send the additional information via e-mail.

According to our records, we requested this detailed agenda on July 26th. It appears that you receive the request over a week ago on July 27th. We were already aware of the items/deficiencies which you intended to discuss but needed additional details to prepare for a meeting.

Tracy Lantz

Regulatory Team 31 Antimicrobials Division

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

"Jeff Jones"

Tracy: Following up on your email to Colleen Sn... 08/04/2011 03:26:30 PM

From: To:

"Jeff Jones" <jjones@delta-ac.com> Tracy Lantz/DC/USEPA/US@EPA

Cc:

Velma Noble/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, ""Snyder Colleen"

<Colleen.Snyder@kemira.com>

Date:

08/04/2011 03:26 PM

Subject:

FW: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills

Tracy:

Following up on your email to Colleen Snyder below, I am writing to request a meeting on Wednesday, Thursday or Friday (10-12 August) next week to address the issues identified below. Within those three days, may I ask that you not schedule the meeting from 1-2 p.m. on Thursday as I already have a conference call with other Agency officials during that time. I understand that scheduling a meeting this quickly is unusual, but we have agreed to make a resubmission by the 28th of August and want to have as much time as possible to organize that submission after the meeting.

We have three primary Agenda items for the meeting:

Kemira's proposed methods for addressing chemistry requirements applicable to its source product

Revised data matrix for addressing other generic data requirements

Timing of reviews (both 1st round and on new submission)

I will submit additional background materials pertaining to each of these agenda items by Monday. I assume that you will invite chemistry reviewers, Velma and Dennis to the meeting and all of these folks will be critical to the success of the meeting. Thanks for your consideration. Let me know if you have questions or need additional information.

Best regards,

Jeff Jones
+1 301 680-7971 V
jjones@delta-ac.com

----Original Message----

From: Snyder Colleen [mailto:Colleen.Snyder@kemira.com]

Sent: Tuesday, July 26, 2011 5:44 PM

To: 'Abramson.Stanley@ArentFox.com'; 'jjones@delta-ac.com'; Keegan Ken Subject: Fw: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

FYI

---- Original Message -----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov)

Sent: Wednesday, July 27, 2011 12:15 AM

To: Snyder Colleen

Cc: Dennis Edwards <Edwards.Dennis@epamail.epa.gov>; Velma Noble

<Noble.Velma@epamail.epa.gov>

Subject: RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

Since we knew that the chemistry data package was incomplete (no data on the source of active ingredient), we did not send it for review, thus there is not a chemistry review to send you at this time. We only send data to review if we feel based on an initial scan that it is a complete package.

In order to schedule a meeting for you we need an agenda. This will help me to assure that the correct individuals are in attendance at the meeting. Please provide as much information as possible in your agenda so that we will be able to adequately discuss your concerns/proposals. (Embedded image moved to file: pic31196.jpg)

From: Snyder Colleen < Colleen. Snyder@kemira.com>

To: Tracy Lantz/DC/USEPA/US@EPA

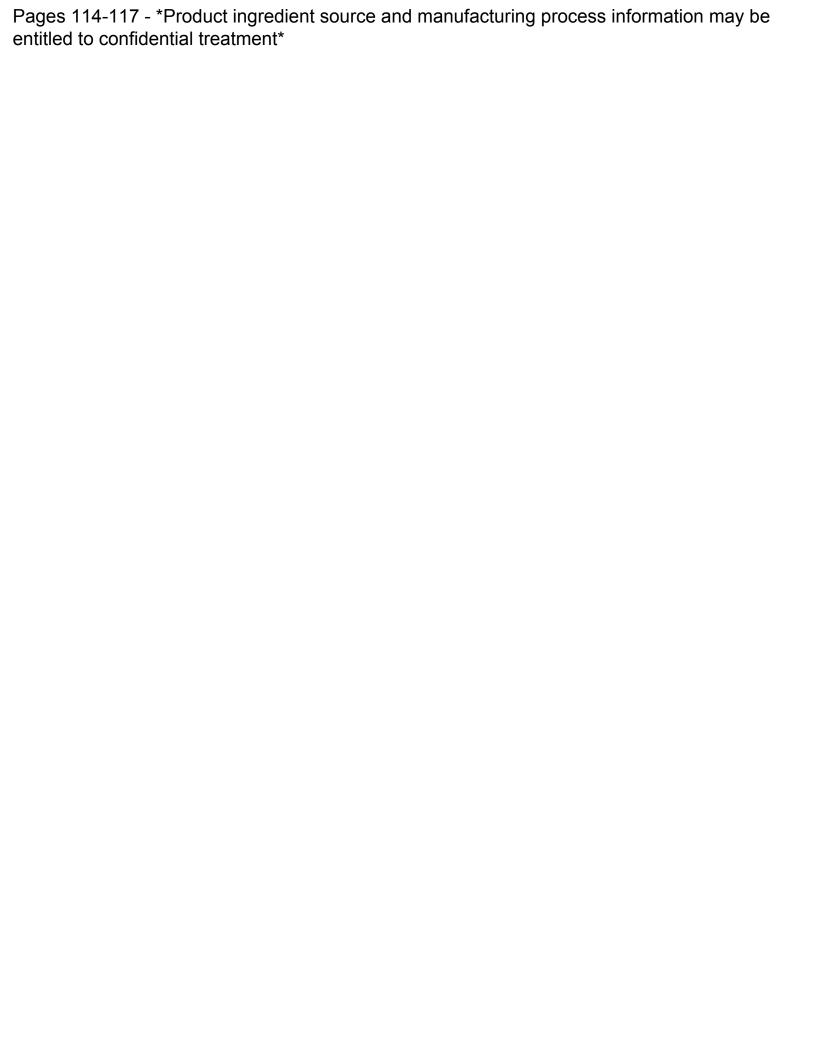
Cc: Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA

Date: 07/26/2011 03:24 PM

Subject: RE: Deficiency letter for 9386-UO Ammonia for use in Pulp

and Paper Mills

Yes Tracy. But I would like to request a meeting as soon as possible to discuss the deficiencies presented in your email. Is mid to late next week good for your schedule?



	Recommendation o Negotiated	of Division Di I Due Dates	rectors		
Decision #: D445675 Registration #:				Petition #:	
See page 2 far additional registration entrie					
Chemical Name: Ammonia					
Fee Category: A532			PRIA De	cision Time F	rame: 120 days
Submitted by: Tracy	Lantz	:: · · · · · · · · · · · · · · ·	Branch:	OCSPP!OPP/AD	Date: 07/29/2011
Company: Kemira Chemicals, Inc.					
Original PRIA Due Date: 08/05		Proposed N	ew PRIA	Due Date: 12/2	23/2011
Previous Negotiated Due Date	s:	- 			
Is the "Fix" in-house? Ye	es 🗸 No 🗌 n/a	If not,	date "Fix"	expected: 08/2	26/2011
Additional Data Required Eff	oduct Chemistry Toxico ficacy Ecolog oduct Chemistry Acute	gical Re	cute Tox esidue ficacy	Environment Other Residue	Toxicology Ask Ve
En	vironmental Ecolog		abeling	✓ Other	Not Submitted Hopet
	Date Risk Assessment				
		ues Environment	tal R	tisk Issues Human	Health
Impurities Review Label Administrative—FR Notice Other—Comment Field					
Summary of Deficiency Type(s	s): Not Submit	tted (N)	Defici	iencies (D)	
Product Chemistry: Acute	Tox: Efficacy: I	Labeling:✓	Ecologica	I Data: Otl	her (describe):🗸
See page two			_		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): See page two					
"75 Day" Letter sent? Yes, Date sent 07/14/2011 No and reason for none? Add camments an page 2					
Rationale for Proposed Due Date: Allow time for fix to arrive and Agency review.					
Registrant notified that this is the last negotiation? Yes Vot Applicable					
Approve: ✓ Disapprove:					
If disapproved, action to be taken:					
OD or DOD Signature: CN=/	Marty Moneil/OU=DC/O=USEPA	VC≃US		Date: 08/02	2/2011

Decision #: D445675	Registration #: 9386-UO	Petition #:	
Issue(s) (describe in detail):			
Registrant needs to correct active ingredient compensation. Company has agreed to add	is statement on label, provide chemistry data on the state of these deficiencies.	ne source material, and generic data	
Describe Interactions with Company: Less than 75 day deficiency letter was e-mailed and sent via USP to company on 7/14/2011, Company representative responded via e-mail on 7/20 and 7/21 and also spoke to Branch Chief Dennis Edwards the same week. Agency replied to company on 7/25 again listing deficiencies and the need for a fix date and renegotiated due date. Company representative and company employee replied on 7/26. A fix date of 8/26 was proposed along with a request for a meeting with the Agency. A regenotiated due date of 12/23/11 was also proposed.			
Comment(s):			

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf Form Number: PRIA

Document Identifier: PRIA-11210102319-TL

SUBMITTED on 07/29/2011 at 11:03:35 AM by CN=Tracy Lantz/OU=DC/O=USEPA/C=US

APPROVED on 07/29/2011 at 02:18:52 PM by CN=Velma Noble/OU=DC/O=USEPA/C=US

APPROVED on 07/29/2011 at 02:22:39 PM by CN=Emily Mitchell/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 08/02/2011 at 07:58:40 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US



RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills
Snyder Colleen to: Tracy Lantz
07/26/2011 03:24 PM

Cc: Dennis Edwards, Velma Noble

Yes Tracy. But I would like to request a meeting as soon as possible to discuss the deficiencies presented in your email. Is mid to late next week good for your schedule?

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Tuesday, July 26, 2011 3:21 PM

To: Snyder Colleen

Cc: Dennis Edwards; Velma Noble

Subject: RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

Thank you for your reply.

Just for clarification, is it correct that your fix will be in house by

8/26/11 and that you are agreeing to a renegotiated due date of

12/23/11 ?

(Embedded image moved to file: pic12508.jpg)

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

"'Abramson, Stanley'" <Abramson.Stanley@ArentFox.com>,
Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA,

Jeff Jones <jjones@delta-ac.com>

Date:

07/26/2011 03:15 PM

Subject:

RE: Deficiency letter for 9386-UO Ammonia for use in Pulp

and Paper Mills

Dear Ms. Lantz,

By way of this email, Kemira Chemicals Inc. hereby notifies EPA that deficiencies as described in your letter of July 14, 2011 will be addressed within 30 days of this email. Kemira Chemicals Inc. also accepts the 120 day time frame as set forth in your e-mail.

Kemira respectfully requests to meet to discuss how best to address the stated deficiencies and would also like the opportunity to review the Product Chemistry Review that promulgated the request for additional data.

Respectfully,

Colleen M Snyder

Product Safety Expert-Biocides, Tissue Specialties North America

Kemira Chemicals Inc

1950 Vaughn Road

Kennesaw, GA 30144 USA Phone: +678 819 4566 Fax: +678 819 4625

email: Colleen.Snyder@Kemira.com

www.kemira.com

----Original Message-----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Tuesday, July 26, 2011 10:56 AM

To: Jeff Jones

Cc: 'Abramson, Stanley'; Snyder Colleen; Dennis Edwards; Velma Noble Subject: RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

I have just spoken with both my team leader, Velma Noble and my branch chief, Dennis Edwards regarding your message below.

Our management will not agree to a renegotiation of less than 120 days for this submission. We believe that 120 days from your fix date is the appropriate time frame, once your chemistry data have been received and assigned MRIDs it will be placed into review with our chemists and will be put into the que behind other submissions which have been received prior to your package. Upon the completion of the review we will be able to either make a decision on your product or will inform you of any additional deficiencies.

If you do not agree to a renegotiated time frame of 120 days from your fix date, I will start the do not grant process today. Please reply by 4:00 PM today.

(Embedded image moved to file: pic32604.jpg)

From: "Jeff Jones" <jjones@delta-ac.com>
To: Dennis Edwards/DC/USEPA/US@EPA

Cc: "'Abramson, Stanley'"

<Abramson.Stanley@ArentFox.com>,

"'Snyder Colleen'" <Colleen.Snyder@kemira.com>, Velma Noble/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA

Date: 07/26/2011 06:47 AM

Subject: RE: Deficiency letter for 9386-UO Ammonia for

use in Pulp

and Paper Mills

Dennis:

I am on vacation, but was able to access the note below from Tracy.

We need some help on the extension issue. As we suspected, two of the three issues identified in the original letter appear to be easily resolvable: a simple label fix and a revised data matrix. The only "deficiency" that might require review outside Velma's team is chemistry and I know those reviews don't take 4 months.

I requested a meeting next week to work out any kinks so that our next submission will be spot-on. Please reconsider that request.

Best regards, Jeff

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Monday, July 25, 2011 9:57 PM

To: Jeff Jones

Cc: 'Abramson, Stanley'; 'Snyder Colleen'; Dennis Edwards; Velma Noble Subject: Re: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills

I spoke with Dennis Edwards today regarding your reply to our deficiency letter. He also indicated that he had spoken to you last week and forwarded your message of 7/21 regarding the prior registrations for ammonium.

Based on our discussions, please address the following:

- 1) Correction of the active ingredients statement on the product label. Submit revised labeling.
- 2) Group A and B chemistry data must be addressed on the source material (AI). You have indicated that you may reply by citing public literature in support of group B. We can not determine at this time whether such citations will meet our data requirements. If our chemistry review indicates that there are still outstanding data requirements, you will be required to submit additional data and renegotiate again. Our management typically approves two renegotiations at most.
- 3) Generic data compensation on the AI must be addressed. It appears that exclusive use data will not be an issue. However you will be required to offer compensation for any data that you do not own.

At this time please reply by indicating when the above information will be provided to the Agency ("a fix date") and indicate that you are willing to renegotiate the current due date for 120 days beyond the date of your submitted fix. This will allow adequate time for our review of your chemistry data, data compensation, product labeling and other required documentation.

Please reply with your fix date and renegotiated due date by COB 7/27. If we have not received your information by that time we will move toward processing a do not grant letter.

Thanks for your prompt attention to these issues. (Embedded image moved to file: picl1833.jpg)

From:

"Jeff Jones"

<jjones@delta-ac.com>

Dennis

Edwards/DC/USEPA/US@EPA

Velma

Cc:
Noble/DC/USEPA/US@EPA, Tracy

Lantz/DC/USEPA/US@EPA,

"'Snyder Colleen'" <Colleen.Snyder@kemira.com>, "'Abramson,

Stanley' < Abramson.Stanley@ArentFox.com>

Date:

07/20/2011 03:24 PM
Deficiency letter for

Subject:

9386-UO Ammonia for use in Pulp and

Paper Mills

(Embedded image moved to file: pic28070.gif) Dear Dennis:

On behalf of Kemira, Inc. I am writing to respond to Tracy Lantz's July 14 email (see below) regarding the pending Kemira application for Fennosurf 586. A letter from Kemira appointing Delta Analytical as its Agent is attached. Tracy suggested that we contact you in her absence this week since the PRIA due date for the application is fast approaching.

Kemira requests a meeting to discuss the three deficiencies Tracy has identified at your earliest convenience:

- 1. Kemira has added a footnote describing its active ingredient on the proposed label which differs from the "me-too"product;
- The Agency claims that Kemira may not use the formulator's exemption to address generic data requirements for an unregistered source of active ingredient (AI); that's obviously correct, but Kemira did not include a formulator's exemption statement in its application; and
- 3. Kemira must provide chemistry data on the unregistered technical source of active ingredient.

I suspect you will agree that resolution of of deficiencies one and two are relatively straightforward. Kemira's product is identical or substantially similar to the "me-too" product and we will label the product as the Agency specifies. Kemira acknowledges that it must address all generic Tier 1 data requirements applicable to its source AI, and intends to use the selective cite-all method of data support to address all applicable requirements.

The third deficiency is the only one which could involve any data review, and might justify extending the PRIA due date. For the reasons stated below, Kemira believes that no extension is necessary:

- The chemistry of ammonia and ammonium sulfate is well-known and well understood
- Kemira proposes to use the equivalent of food-grade ammonium sulfate as its source of active ingredient
- Kemira has supplied data on its source material including a certificate of analysis which demonstrates that this source meets all Food Chemical Codex specifications

Kemira understands that EPA does not routinely require product chemistry data for food -grade sources of active ingredient

As you consider our request for relief from the 4-month extension proposal, I should also point out that I find it surprising that Kemira was not notified

of a chemistry data deficiency until more than 3 months into the PRIA review period. The timing of this chemistry review and finding seems to have departed from my typical experience (chemistry reviews usually completed in 30-60 days after expiration of the screening period).

May we schedule a call early the week of August 1 to discuss these issues and hopefully work out a mutually satisfactory path forward. Thanks for your consideration.

Best regards,

Jeff Jones
Delta Analytical Corporation
+1 301 680-7971 V
jjones@delta-ac.com

----Original Message----

From: Tracy Lantz (mailto:Lantz.Tracy@epamail.epa.gov)

Sent: Thursday, July 14, 2011 5:56 PM

To: Snyder Colleen

Subject: Fw: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

You will receive a hard copy of this letter in the mail shortly. I will be away from the office the week of 7/18. In my absence you may contact Dennis Edwards or Velma Noble.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject: Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on August 5, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter.

Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it.

Address the following deficiencies:

Me-Too Status

You have indicated that your formula is substantially similar to Buckman Laboratories Busan 1215 (EPA Reg. # 1448-433). The Buckman product lists the active ingredient as "Ammonia (total) ...7.59%". If your product is a "me-too" of this Buckman product, your label should read exactly the same without a footnote stating: "(as Ammonium Sulfate (29.5%))" Please clarify the active ingredient in your formulation.

Chemistry Data on the Source Material

Your formulation does not utilize an EPA registered source of active ingredient. Therefore you must provide chemistry data on the unregistered technical source of active ingredient. We will use this information to make a determination as to whether or not your product is similar to other registered known sources of this active ingredient. Your application includes chemistry data on the formula you intend to register (7.59%), but not on the technical source

Generic Data Compensation

You may not address generic data compensation using the Formulator's Exemption Statement since you are not purchasing a registered source of active ingredient. In order to register this product you are required to support all of the Tier I Data Requirements on the technical source. Please be aware that there may be some exclusive use data associated with the data submitted by Buckman in support of their Busan 1215 product. Buckman could provide you with a permission letter as per FIFRA 3(c) (f) (i). We are in the process of clarifying the exclusive use status of the Buckman data. We will notify you soon.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on August 5, 2011. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. Establish a new due date. You may resolve the issues identified in this letter by submitting a reply to the Agency by July 25, 2011 with information as how you plan to address these deficiencies. Please include your proposed re-negotiated PRIA due date of an additional 120 days for review beyond the date you expect the fix to arrive. Also indicate when you expect your fix to arrive at the Agency for review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution

of the deficiencies will result in the granting of your application.

- 2. Withdraw the application. Alternatively, you may notify us not later than July 25, 2011 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.
- 3. Not respond. If the Agency does not hear from you by July 25, 2011, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by July 25, 2011 by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov , Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov or Dennis Edwards by telephone at (703)

308-8087 or by e-mail at Edwards.dennis@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

(Embedded image moved to file: pic06923.jpg)

No virus found in this incoming message.

Checked by AVG - www.avg.com

Version: 9.0.901 / Virus Database: 271.1.1/3765 - Release Date: 07/15/11 02:34:00

(See attached file: Kemira Agent appoinment letter 15 Jul 2011.pdf)

9386-00 renegotiation request

Created pdf

to fee for service form



RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills
Snyder Colleen to: Tracy Lantz
07/26/2011 03:24 PM
Cc: Dennis Edwards, Velma Noble

Yes Tracy. But I would like to request a meeting as soon as possible to discuss the deficiencies presented in your email. Is mid to late next week good for your schedule?

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Tuesday, July 26, 2011 3:21 PM

To: Snyder Colleen

Cc: Dennis Edwards; Velma Noble

Subject: RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

Thank you for your reply. Just for clarification, is it correct that your fix will be in house by 8/26/11 and that you are agreeing to a renegotiated due date of 12/23/11?

(Embedded image moved to file: picl2508.jpg)

From:

Snyder Colleen < Colleen. Snyder@kemira.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Cc:

"'Abramson, Stanley'" <Abramson.Stanley@ArentFox.com>,

Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA,

Jeff Jones <jjones@delta-ac.com>

Date:

07/26/2011 03:15 PM

Subject:

RE: Deficiency letter for 9386-UO Ammonia for use in Pulp

and Paper Mills

Dear Ms. Lantz,

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Kemira respectfully requests to meet to discuss how best to address the stated deficiencies and would also like the opportunity to review the Product Chemistry Review that promulgated the request for additional data.

Respectfully,

Colleen M Snyder Product Safety Expert-Biocides, Tissue Specialties North America

Kemira Chemicals Inc

1950 Vaughn Road Kennesaw, GA 30144 USA Phone: +678 819 4566 Fax: +678 819 4625

email: Colleen.Snyder@Kemira.com

www.kemira.com

----Original Message-----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Tuesday, July 26, 2011 10:56 AM

To: Jeff Jones

Cc: 'Abramson, Stanley'; Snyder Colleen; Dennis Edwards; Velma Noble

Subject: RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

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I have just spoken with both my team leader, Velma Noble and my branch chief, Dennis Edwards regarding your message below.

Our management will not agree to a renegotiation of less than 120 days for this submission. We believe that 120 days from your fix date is the appropriate time frame, once your chemistry data have been received and assigned MRIDs it will be placed into review with our chemists and will be put into the que behind other submissions which have been received prior to your package. Upon the completion of the review we will be able to either make a decision on your product or will inform you of any additional deficiencies.

If you do not agree to a renegotiated time frame of 120 days from your fix date, I will start the do not grant process today. Please reply by 4:00 PM today.

(Embedded image moved to file: pic32604.jpg)

From: "Jeff Jones" <jjones@delta-ac.com>
To: Dennis Edwards/DC/USEPA/US@EPA

Cc: "'Abramson, Stanley'"

<Abramson.Stanley@ArentFox.com>,

"'Snyder Colleen'" <Colleen.Snyder@kemira.com>, Velma Noble/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA

Date: 07/26/2011 06:47 AM

Subject: RE: Deficiency letter for 9386-UO Ammonia for

use in Pulp

and Paper Mills

Dennis:

I am on vacation, but was able to access the note below from Tracy.

We need some help on the extension issue. As we suspected, two of the three issues identified in the original letter appear to be easily resolvable: a simple label fix and a revised data matrix. The only "deficiency" that might require review outside Velma's team is chemistry and I know those reviews don't take 4 months.

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From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Monday, July 25, 2011 9:57 PM

To: Jeff Jones

Cc: 'Abramson, Stanley'; 'Snyder Colleen'; Dennis Edwards; Velma Noble Subject: Re: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills

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- 1) Correction of the active ingredients statement on the product label. Submit revised labeling.
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Please reply with your fix date and renegotiated due date by COB 7/27. If we have not received your information by that time we will move toward processing a do not grant letter.

Thanks for your prompt attention to these issues. (Embedded image moved to file: picl1833.jpg)

From:

"Jeff Jones"

<jjjones@delta-ac.com>

Dennis

Edwards/DC/USEPA/US@EPA

Velma

Noble/DC/USEPA/US@EPA, Tracy

Lantz/DC/USEPA/US@EPA,

"'Snyder Colleen'" <Colleen.Snyder@kemira.com>, "'Abramson,

Stanley'" <Abramson.Stanley@ArentFox.com>

Date: Subject:

Cc:

07/20/2011 03:24 PM

Deficiency letter for

9386-UO Ammonia for use in Pulp and

Paper Mills

(Embedded image moved to file: pic28070.gif) Dear Dennis:

On behalf of Kemira, Inc. I am writing to respond to Tracy Lantz's July 14 email (see below) regarding the pending Kemira application for Fennosurf 586. A letter from Kemira appointing Delta Analytical as its Agent is attached. Tracy suggested that we contact you in her absence this week since the PRIA due date for the application is fast approaching.

Kemira requests a meeting to discuss the three deficiencies Tracy has identified at your earliest convenience:

- 1. Kemira has added a footnote describing its active ingredient on the proposed label which differs from the "me-too"product;
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I suspect you will agree that resolution of of deficiencies one and two are relatively straightforward. Kemira's product is identical or substantially similar to the "me-too" product and we will label the product as the Agency specifies. Kemira acknowledges that it must address all generic Tier 1 data requirements applicable to its source AI, and intends to use the selective cite-all method of data support to address all applicable requirements.

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• Kemira understands that EPA does not routinely require product chemistry data for food -grade sources of active ingredient

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of a chemistry data deficiency until more than 3 months into the PRIA review period. The timing of this chemistry review and finding seems to have departed from my typical experience (chemistry reviews usually completed in 30-60 days after expiration of the screening period).

May we schedule a call early the week of August 1 to discuss these issues and hopefully work out a mutually satisfactory path forward. Thanks for your consideration.

Best regards,

Jeff Jones Delta Analytical Corporation +1 301 680-7971 V jjones@delta-ac.com

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, July 14, 2011 5:56 PM

To: Snyder Colleen

Subject: Fw: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

You will receive a hard copy of this letter in the mail shortly. I will be away from the office the week of 7/18. In my absence you may contact Dennis Edwards or Velma Noble.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject: Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on August 5, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter.

Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections to complete the application, or notifying the Agency of the date on which you expect to

complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it.

Address the following deficiencies:

Me-Too Status

You have indicated that your formula is substantially similar to Buckman Laboratories Busan 1215 (EPA Reg. # 1448-433). The Buckman product lists the active ingredient as "Ammonia (total) ...7.59%". If your product is a "me-too" of this Buckman product, your label should read exactly the same without a footnote stating: "(as Ammonium Sulfate (29.5%))" Please clarify the active ingredient in your formulation.

Chemistry Data on the Source Material

Your formulation does not utilize an EPA registered source of active ingredient. Therefore you must provide chemistry data on the unregistered technical source of active ingredient. We will use this information to make a determination as to whether or not your product is similar to other registered known sources of this active ingredient. Your application includes chemistry data on the formula you intend to register (7.59%), but not on the technical source

Generic Data Compensation

You may not address generic data compensation using the Formulator's Exemption Statement since you are not purchasing a registered source of active ingredient. In order to register this product you are required to support all of the Tier I Data Requirements on the technical source. Please be aware that there may be some exclusive use data associated with the data submitted by Buckman in support of their Busan 1215 product. Buckman could provide you with a permission letter as per FIFRA 3(c) (f) (i). We are in the process of clarifying the exclusive use status of the Buckman data. We will notify you soon.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on August 5, 2011. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. Establish a new due date. You may resolve the issues identified in this letter by submitting a reply to the Agency by July 25, 2011 with information as how you plan to address these deficiencies. Please include your proposed re-negotiated PRIA due date of an additional 120 days for review beyond the date you expect the fix to arrive. Also indicate when you expect your fix to arrive at the Agency for review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution

of the deficiencies will result in the granting of your application.

- 2. Withdraw the application. Alternatively, you may notify us not later than July 25, 2011 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.
- 3. Not respond. If the Agency does not hear from you by July 25, 2011, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by July 25, 2011 by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov , Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov or Dennis Edwards by telephone at (703)

308-8087 or by e-mail at Edwards.dennis@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

(Embedded image moved to file: pic06923.jpg)

No virus found in this incoming message. Checked by AVG - www.avg.com

Version: 9.0.901 / Virus Database: 271.1.1/3765 - Release Date: 07/15/11 02:34:00

(See attached file: Kemira Agent appoinment letter 15 Jul 2011.pdf)



RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills Tracy Lantz to: Jeff Jones 07/26/2011 10:55 AM

"'Abramson, Stanley", "'Snyder Colleen", Dennis Edwards, Velma Cc: Noble

I have just spoken with both my team leader, Velma Noble and my branch chief, Dennis Edwards regarding your message below.

Our management will not agree to a renegotiation of less than 120 days for this submission. We believe that 120 days from your fix date is the appropriate time frame, once your chemistry data have been received and assigned MRIDs it will be placed into review with our chemists and will be put into the que behind other submissions which have been received prior to your package. Upon the completion of the review we will be able to either make a decision on your product or will inform you of any additional deficiencies.

If you do not agree to a renegotiated time frame of 120 days from your fix date, I will start the do not grant process today.

Please reply by 4:00 PM today.

Draw Lax

Tracy Lantz

Regulatory Team 31 **Antimicrobials Division**

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

"Jeff Jones"

Dennis: I am on vacation, but was able to acces... 07/26/2011 06:47:36 AM

From: To:

"Jeff Jones" <jjones@delta-ac.com>

Dennis Edwards/DC/USEPA/US@EPA

Cc:

"'Abramson, Stanley'" <Abramson.Stanley@ArentFox.com>, "'Snyder Colleen" <Colleen.Snyder@kemira.com>, Velma Noble/DC/USEPA/US@EPA, Tracy

Lantz/DC/USEPA/US@EPA

Date:

07/26/2011 06:47 AM

Subject:

RE: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills

Dennis:

I am on vacation, but was able to access the note below from Tracy.

We need some help on the extension issue. As we suspected, two of the three issues identified in the original letter appear to be easily resolvable: a simple label fix and a revised data matrix. The only "deficiency" that might require review outside Velma's team is chemistry and I know those reviews don't take 4 months.

I requested a meeting next week to work out any kinks so that our next submission will be spot-on. Please reconsider that request.

Best regards,

Jeff

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Monday, July 25, 2011 9:57 PM

To: Jeff Jones

Cc: 'Abramson, Stanley'; 'Snyder Colleen'; Dennis Edwards; Velma Noble Subject: Re: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills

I spoke with Dennis Edwards today regarding your reply to our deficiency letter. He also indicated that he had spoken to you last week and forwarded your message of 7/21 regarding the prior registrations for ammonium.

Based on our discussions, please address the following:

- 1) Correction of the active ingredients statement on the product label. Submit revised labeling.
- 2) Group A and B chemistry data must be addressed on the source material (AI]. You have indicated that you may reply by citing public literature in support of group B. We can not determine at this time whether such citations will meet our data requirements. If our chemistry review indicates that there are still outstanding data requirements, you will be required to submit additional data and renegotiate again. Our management typically approves two renegotiations at most.
- 3) Generic data compensation on the AI must be addressed. It appears that exclusive use data will not be an issue. However you will be required to offer compensation for any data that you do not own.

At this time please reply by indicating when the above information will be provided to the Agency ("a fix date") and indicate that you are willing to renegotiate the current due date for 120 days beyond the date of your submitted fix. This will allow adequate time for our review of your chemistry data, data compensation, product labeling and other required documentation.

Please reply with your fix date and renegotiated due date by COB 7/27. If we have not received your information by that time we will move toward processing a do not grant letter.

Thanks for your prompt attention to these issues. (Embedded image moved to file: picl1833.jpg)

From: "Jeff Jones" <jjones@delta-ac.com>
To: Dennis Edwards/DC/USEPA/US@EPA

Cc: Velma Noble/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA,

"'Snyder Colleen'" <Colleen.Snyder@kemira.com>, "'Abramson,

Stanley'" <Abramson.Stanley@ArentFox.com>

Date: 07/20/2011 03:24 PM

Subject: Deficiency letter for 9386-UO Ammonia for use in Pulp and

Paper Mills

(Embedded image moved to file: pic28070.gif) Dear Dennis:

On behalf of Kemira, Inc. I am writing to respond to Tracy Lantz's July 14 email (see below) regarding the pending Kemira application for Fennosurf 586. A letter from Kemira appointing Delta Analytical as its Agent is attached. Tracy suggested that we contact you in her absence this week since the PRIA due date for the application is fast approaching.

Kemira requests a meeting to discuss the three deficiencies Tracy has identified at your earliest convenience:

- 1. Kemira has added a footnote describing its active ingredient on the proposed label which differs from the "me-too"product;
- 2. The Agency claims that Kemira may not use the formulator's exemption to address generic data requirements for an unregistered source of active ingredient (AI); that's obviously correct, but Kemira did not include a formulator's exemption statement in its application; and
- 3. Kemira must provide chemistry data on the unregistered technical source of active ingredient.

I suspect you will agree that resolution of of deficiencies one and two are relatively straightforward. Kemira's product is identical or substantially similar to the "me-too" product and we will label the product as the Agency specifies. Kemira acknowledges that it must address all generic Tier 1 data requirements applicable to its source AI, and intends to use the selective cite-all method of data support to address all applicable requirements.

The third deficiency is the only one which could involve any data review, and might justify extending the PRIA due date. For the reasons stated below, Kemira believes that no extension is necessary:

- The chemistry of ammonia and ammonium sulfate is well-known and well understood
- Kemira proposes to use the equivalent of food-grade ammonium sulfate as its source of active ingredient
- Kemira has supplied data on its source material including a certificate of analysis which demonstrates that this source meets all Food Chemical Codex specifications

• Kemira understands that EPA does not routinely require product chemistry data for food -grade sources of active ingredient

As you consider our request for relief from the 4-month extension proposal, I should also point out that I find it surprising that Kemira was not notified of a chemistry data deficiency until more than 3 months into the PRIA review period. The timing of this chemistry review and finding seems to have departed from my typical experience (chemistry reviews usually completed in 30-60 days after expiration of the screening period).

May we schedule a call early the week of August 1 to discuss these issues and hopefully work out a mutually satisfactory path forward. Thanks for your consideration.

Best regards,

Jeff Jones Delta Analytical Corporation +1 301 680-7971 V jjones@delta-ac.com

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, July 14, 2011 5:56 PM

To: Snyder Colleen

Subject: Fw: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

You will receive a hard copy of this letter in the mail shortly. I will be away from the office the week of 7/18. In my absence you may contact Dennis Edwards or Velma Noble.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject: H

Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

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Please respond to this letter by July 25, 2011 by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov, Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov or Dennis Edwards by telephone at (703) 308-8087 or by e-mail at Edwards.dennis@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing. (Embedded image moved to file: pic06923.jpg)

No virus found in this incoming message. Checked by AVG - www.avg.com Version: 9.0.901 / Virus Database: 271.1.1/3765 - Release Date: 07/15/11 02:34:00

(See attached file: Kemira Agent appoinment letter 15 Jul 2011.pdf)



Fw: Kemira follow-up; exclusive use issue

Dennis Edwards to: Tracy Lantz

Cc: Velma Noble

07/25/2011 04:17 PM

Dennis Edwards, Chief Regulatory Management Branch 1 Antimicrobials Division 703-308-8087

---- Forwarded by Dennis Edwards/DC/USEPA/US on 07/25/2011 04:17 PM ----

From:

"Jeff Jones" <jjones@delta-ac.com>

To:

Dennis Edwards/DC/USEPA/US@EPA

Date:

07/21/2011 11:39 AM

Subject:

Kemira follow-up; exclusive use issue

Dennis:

After our conversation this morning, I did the attached NPIRS search on all prior ammonia registrations; none are still active except the Buckman products.

The search indicates that ammonia was first registered as an active on January 1, 1976. Since that was prior to 1978, the exclusive use provisions later enacted, do not appear to apply. I hope you'll be able to confirm that with Mark Diner later today.

Thanks for your consideration.

Best regards,

Jeff Jones Delta Analytical Corporation +1 301 680-7971 V jjones@delta-ac.com



NPIRS search for all ammonia registrations 21 Jul 2011.htm

Federal Registration Data



Date of Search: 07/21/11 Time of Search: 11:26

Number of Products Selected: 6

Federal Data

Ingredient: AMMONIA

BCMW

£PA REG NO: 1448-432 NAME STATUS: PRIMARY NAME

PRODUCT STATUS: ACTIVE

REGISTRANT: BUCKMAN LABORATORIES INC.

1256 NORTH MCLEAN BLVD

MEMPHIS TN 38108

FORMULATION: FORMULATION INTERMEDIATE

SIGNAL WORD: CAUTION

TYPES: BACTERIOCIDE/BACTERIOSTAT

PERCENT ACTIVE INGREDIENT 7.5900 Ammonia (5302)

STATES REG: NONE

ORIGINAL APPROVAL DATE: 03-06-07

MOST RECENT ACCEPT DATE: ** NA ** USES LAST UPDATED BY EPA: ** NA **

USES

FORMULATING USE ONLY NO SITE
**** END OF DATA FOR THIS PRODUCT ****

BUSAN 1215

EPA REG NO: 1448-433 NAME STATUS: PRIMARY NAME

PRODUCT STATUS: ACTIVE

REGISTRANT: BUCKMAN LABORATORIES INC.

1256 NORTH MCLEAN BLVD

MEMPHIS TN 38108

FORMULATION: SOLUBLE CONCENTRATE

SIGNAL WORD: CAUTION

TYPES: MICROBICIDE

PERCENT ACTIVE INGREDIENT 7.5900 Annonia (5302)

STATES REG: IN-11 OR-11 PA-11 SC-10 MN-11 WA-12 MA-11 WI-11 GA-11 MI-12

OH-12 AZ-12 TX-12 WV-11 ME-11 NV-11 ID-11 NY-12 TA-11 LA-11

KS-11

ORIGINAL APPROVAL DATE: 03-06-07 MOST RECENT ACCEPT DATE: ** NA **

USES LAST UPDATED BY EPA: 07-11-11

NAME STATUS: PRIMARY NAME

USES

FOOD PROCESSING WATER SYSTEMS
BREWERY PASTEURIZER WATER
PASTEURIZER WATER
PULP AND PAPER MILL SYSTEMS
INDUSTRIAL WASTE DISPOSAL SYSTEMS
AIR WASHER WATER
COOLING TOWER WATER

EVAPORATIVE CONDENSER WATER SYSTEMS

ORNAMENTAL FOUNTAINS

SEWAGE SYSTEMS (WATER TREATMENT) INDUSTRIAL WATER (UNSPECIFIED)

PONDS (SMALL) (NON-FISH BEARING) (WATER TREATMENT)

PAPER/PAPERBOARD (FOOD CONTACT SURFACES)

**** END OF DATA FOR THIS PRODUCT ****

AANKILL 44

EPA REG NO: 63709-1

PRODUCT STATUS: CANCELLED ON: 07-18-06 EXISTING STOCKS DATE: ** NA ** REASON FOR CANCELLATION: REGISTRANT REQUEST / NONPAYMENT OF MAINT. FEE

REGISTRANT: DLT LABORATORIES

ATTN: DANA L. TURNER

511 CROSSKEYS CLINTON MS 39056

FORMULATION: EMULSIFIABLE CONCENTRATE

SIGNAL WORD: CAUTION

TYPES: UNCLASSIFIED

CONDITIONALLY REGISTERED - FIFRA 3(c)7

INSECTICIDE MITICIDE

PERCENT ACTIVE INGREDIENT 0.2000 Ammonia (5302) 14.2000 Turpentine (84501)

STATES REG: AR-02 GA-04 FL-04

ORIGINAL APPROVAL DATE: 07-25-94

MOST RECENT ACCEPT DATE: ID-00-94 USES LAST UPDATED BY EPA: "* NA **

USES

ANT HILLS

**** END OF DATA FOR THIS PRODUCT ****

DEXOL SUPER

EPA REG NO: 192-7482 (CA) NAME STATUS: PRIMARY NAME

PRODUCT STATUS: CANCELLED ON: 07-01-87 EXISTING STOCKS DATE: ** NA ** REASON FOR CANCELLATION: GENERIC DATA EXEMPTION CALL-IN

REGISTRANT: VALUE GARDENS SUPPLY, LLC

D/B/A VALUE GARDEN SUPPLY

PO BOX 585 SAINT JOSEPH MO 64502 FORMULATION: EMULSIFIABLE CONCENTRATE SIGNAL WORD: DANGER TYPES: MITICIDE INSECTICIDE PERCENT ACTIVE INGREDIENT 0.8000 Ammonia (5302) 1.2000 Nicotine (56702) 67.5000 Mineral oil - includes paraffin oil from 063503 (63502) STATES REG: NONE ORIGINAL APPROVAL DATE: 01-01-76 MOST RECENT ACCEPT DATE: 01-00-76 USES LAST UPDATED BY EPA: 07-01-87 USES GRAPEFRUIT (FOLIAR TREATMENT) LEMONS (FOLIAR TREATMENT) LIMES (FOLIAR TREATMENT) ORANGES (FOLIAR TREATMENT) ALMONDS (FOLIAR TREATMENT) APPLES (FOLIAR TREATMENT) PEARS (FOLIAR TREATMENT) APRICOTS (FOLIAR TREATMENT) PEACHES (FOLIAR TREATMENT) PLUMS (FOLIAR TREATMENT) ORNAMENTAL WOODY SHRUBS (FOLIAR TREATMENT) ORNAMENTAL BROADLEAF EVERGREEN SHRUBS (FOLIAR TREATMENT) AZALEA (FOLIAR TREATMENT) CAMELLIA (FOLIAR TREATMENT) GARDENIA (FOLIAR TREATMENT) OAK (FOLIAR TREATMENT) **** END OF DATA FOR THIS PRODUCT **** REPEL EPA REG NO: 1148-7186 (CA) NAME STATUS: PRIMARY NAME PRODUCT STATUS: CANCELLED ON: 03-16-87 EXISTING STOCKS DATE: ** NA ** REASON FOR CANCELLATION: OTHER AGENCY ACTION REGISTRANT: LEFFINGWELL C/O UNIROYAL CHEMICAL CO., INC. 74 AMITY ROAD BETHANY CT 06525 FORMULATION: SOLUBLE CONCENTRATE SIGNAL WORD: CAUTION TYPES: REPELLENT PERCENT ACTIVE INGREDIENT 1.5000 Ammorria (5302) 13.0000 Copper salts of fatty and rosin acids (23104) STATES REG: NONE ORIGINAL APPROVAL DATE: 01-01-76

```
MOST RECENT ACCEPT DATE: 01-00-76 USES LAST UPDATED BY EPA: 03-16-87
    USES
       GRAPES (FOLIAR TREATMENT)
       GRAPES (TABLE) (FOLIAR TREATMENT)
       GRAIN CROPS (FOLIAR TREATMENT)
       VEGETABLE CROFS (FOLIAR TREATMENT)
       FRUIT TREES (FOLIAR TREATMENT)
       FRUIT TREES (DECIDUOUS) (DORMANT APPLICATION)
       FORAGE CROPS (FOLIAR TREATMENT)
       ORNAMENTAL PLANTS (NURSERY STOCK)
       ORNAMENTAL WOODY SHRUBS (FOLIAR TREATMENT)
       ORNAMENTAL BROADLEAF EVERGREEN SHRUBS (FOLIAR TREATMENT)
       ORNAMENTAL TREES (TRUNKS)
       ORNAMENTAL BROADLEAF EVERGREEN TREES (BASAL BARK APPLICATION)
       ORNAMENTAL CONIFERS (BASAL BARK APPLICATION)
      NONCROP AREAS
**** END OF DATA FOR THIS PRODUCT ****
OLD PRO DORMANT SPRAY
 EPA REG NO: 29356-3707 ( TX )
                                          NAME STATUS: PRIMARY NAME
  PRODUCT STATUS: CANCELLED ON: 10-02-80 EXISTING STOCKS DATE: ** NA **
  REASON FOR CAMCELLATION:
                            EFA LETTER
    REGISTRANT: HURT CHEMICAL COMPANY
                ODESSA TX 79760
   FORMULATION: EMULSIFIABLE CONCENTRATE
   SIGNAL WORD: WARNING
   TYPES: FUNGICIDE
          MITICIDE
          INSECTICIDE
    PERCENT ACTIVE INGREDIENT
    0.9000 Ammonia (5302)
    67.0000 Mineral oil - includes paraffin oil from 063503 (63502)
    0.9000 Pine oil (67002)
    1.0000 Calcium polysulfide (76702)
   STATES REG: NONE
   ORIGINAL APPROVAL DATE: 01-01-76
   MOST RECENT ACCEPT DATE: 01-00-76 USES LAST UPDATED BY EPA: ** NA **
   NO USE DATA AVAILABLE
*** END OF DATA FOR THIS PRODUCT ****
*** END OF CUTPUT ***
```

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Re: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills Tracy Lantz to: Jeff Jones 07/25/2011 09:57 PM

Co: "Abramson, Stanley", "Snyder Colleen", Dennis Edwards, Velma

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Thanks for your prompt attention to these issues.

Tracy Lantz

Regulatory Team 31
Antimicrobials Division

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

"Jeff Jones"

Dear Dennis:

07/20/2011 03:24:33 PM

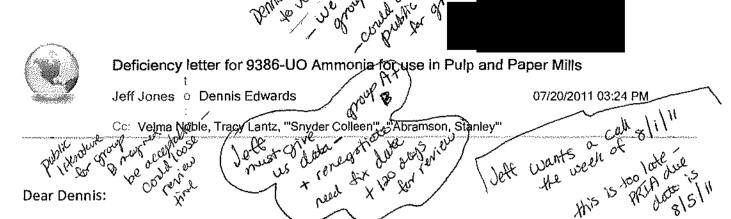
From: "Jeff Jones" <jjones@delta-ac.com>
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Cc: Velma Noble/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, ""Snyder Colleen""

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Subject: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills



On behalf of Kemira, Inc. I am writing to respond to Tracy Lantz's July 14 email (see below) regarding the pending Kemira application for Fennosurf 586. A letter from Kemira appointing Delta Analytical as its Agent is attached. Tracy suggested that we contact you in her absence this week since the PRIA due date for the application is fast approaching.

Kemira requests a meeting to discuss the three deficiencies Tracy has identified at your earliest convenience:

- 1. Kemira has added a footnote describing its active ingredient on the proposed label which differs from the "me-too" product;
- 2. The Agency claims that Kemira may not use the formulator's exemption to address generic data requirements for an unregistered source of active ingredient (AI); that's obviously correct, but Kemira did not include a formulator's exemption statement in its application; and
- Kemira must provide chemistry data on the unregistered technical source of active ingredient.

I suspect you will agree that resolution of of deficiencies one and two are relatively straightforward. Kemira's product is identical or substantially similar to the "me-too" product and we will label the product as the Agency specifies. Kemira acknowledges that it must address all generic Tier 1 data requirements applicable to its source AI, and intends to use the selective cite-all method of data support to address all applicable requirements.

The third deficiency is the only one which could involve any data review, and might justify \mathcal{A} extending the PRIA due date. For the reasons stated below, Kemira believes that no extension is necessary:

- The chemistry of ammonia and ammonium sulfate is well-known and well understood
- Kemira proposes to use the equivalent of food-grade ammonium sulfate as its source of active ingredient
- Kemira has supplied data on its source material including a certificate of analysis which demonstrates that this source meets all Food Chemical Codex specifications

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 Kemira understands that EPA does not routinely require product chemistry data for food -grade sources of active ingredient

As you consider our request for relief from the 4-month extension proposal, I should also point out that I find it surprising that Kemira was not notified of a chemistry data deficiency until more than 3 months into the PRIA review period. The timing of this chemistry review and finding seems to have departed from my typical experience (chemistry reviews usually completed in 30-60 days after expiration of the screening period).

May we schedule a call early the week of August 1 to discuss these issues and hopefully work out a mutually satisfactory path forward. Thanks for your consideration.

Best regards,

Jeff Jones Delta Analytical Corporation +1 301 680-7971 V jjones@delta-ac.com

----Original Message----

From: Tracy Lantz [mailto:Lantz.Tracy@epamail.epa.gov]

Sent: Thursday, July 14, 2011 5:56 PM

To: Snyder Colleen

Subject: Fw: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper

Mills

You will receive a hard copy of this letter in the mail shortly. I will be away from the office the week of 7/18. In my absence you may contact Dennis Edwards or Velma Noble.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject: Fennosurf 586

EPA File 5ymbol: 9386-U0

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

Dear Ms. Snyder:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on August 5, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter.

Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

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Address the following deficiencies:

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Generic Data Compensation

You may not address generic data compensation using the Formulator's Exemption Statement since you are not purchasing a registered source of active ingredient. In order to register this product you are required to support all of the Tier I Data

Requirements on the technical source. Please be aware that there may be some exclusive use data associated with the data submitted by Buckman in support of their Busan 1215 product. Buckman could provide you with a permission letter as per FIFRA 3(c) (f) (i). We are in the process of clarifying the exclusive use status of the Buckman data. We will notify you soon.

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application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by July 25, 2011 by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov, Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov or Dennis Edwards by telephone at (703) 308-8087 or by e-mail at Edwards.dennis@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

(Embedded image moved to file: pic06923.jpg)

No virus found in this incoming message.

Checked by AVG - www.avg.com

Version: 9.0.901 / Virus Database: 271.1.1/3765 - Release Date: 07/15/11

02:34:00



Kemira Agent appoinment letter 15 Jul 2011.pdf

Product Safety

July 15, 2011

Antimicrobial Division
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

Dear Sir or Madam:

I appoint:

Delta Analytical Corporation 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Telephone:

301 680-7971

Fax:

301 680-7975

as Kemira, Inc.'s agent for pesticide registration matters. Jeff Jones and Donna Leventhal of Delta will be your primary contacts.

My best regards,

Colleen M. Snyder

Product Safety Expert-Biocides

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

JUL 14 2011

Subject:

Fennosurf 586

EPA File Symbol: 9386-UO

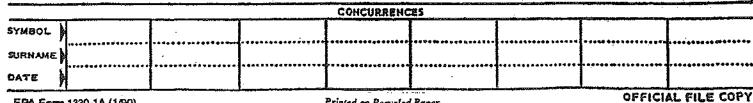
Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

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EPA Form 1320-1A (1/90)

Printed on Recycled Paper

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Me-Too Status

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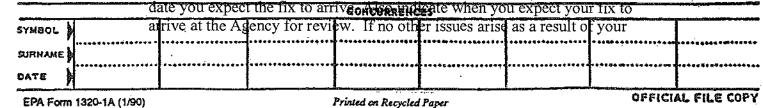
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154

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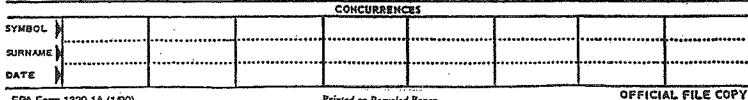
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Sincerely,

Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P)

7510P: T.Lantz:7/14/11 9386-UO less than 75 deficiency letter



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

155



Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills

Tracy Lantz to: colleen.synder Cc: Dennis Edwards, Velma Noble

07/14/2011 05:54 PM

You will receive a hard copy of this letter in the mail shortly.

I will be away from the office the week of 7/18. In my absence you may contact Dennis Edwards or Velma Noble.

OPP Decision Number D445675

Colleen Snyder Kemira Chemicals Inc. 1950 Vaughn Road Kennesaw, GA 30144

Subject:

Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

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Tracy Lantz

Regulatory Team 31
Antimicrobials Division

Dray Lants

U.S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481



Fw: Deficiency letter for 9386-UO Ammonia for use in Pulp and Paper Mills
Tracy Lantz to: colleen.snyder 07/14/2011 05:55 PM

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Fennosurf 586

EPA File Symbol: 9386-UO

Application Dated: February 17, 2011 EPA Receipt Date: February 22, 2011

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Tracy Lantz

Regulatory Team 31
Antimicrobials Division

Dray Lants

U.S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481



Re: two areas of questions in red... Re: See question in red---please reply today. Re: initial comments included... Re: Kemira application for registration

Dennis Edwards to: Philip Ross Cc: Kim Wilson, Tracy Lantz, Velma Noble 06/02/201 t 03:19 PM

Phil,

Dennis

Dennis Edwards, Chief Regulatory Management Branch 1 Antimicrobials Division 703-308-8087

Philip Ross

Attorney Client Communication Attorney Work P...

06/02/2011 01:19:49 PM

From:

Philip Ross/DC/USEPA/US

To:

Dennis Edwards/DC/USEPA/US@EPA, Kim Wilson/DC/USEPA/US@EPA, Tracy

Lantz/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA

Date:

06/02/2011 01:19 PM

Subject:

two areas of questions in red... Re: See question in red--please reply today. Re: initial comments

included... Re: Kemira application for registration

Attorney Client Communication Attorney Work Product Deliberative Privileged and Confidential Do Not Release

Dennis--



Thanks!

Phil

Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office



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Dennis Edwards, Kim Wilson, Tracy Lantz, Velma Philip Ross to:

06/02/2011 0t:19 PM

Attorney Client Communication Attorney Work Product Deliberative Privileged and Confidential Do Not Release

Dennis---



Thanks!

Phil

Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office 202-564-5637

Philip Ross

Attorney Client Communication Attorney Work... 06/02/2011 09:34:16 AM

From:

Philip Ross/DC/USEPA/US

To:

Dennis Edwards/DC/USEPA/US@EPA

Cc:

Tracy Lantz/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Kim

Wilson/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA

Date:

06/02/201 t 09:34 AM

Subject:

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for registration

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Dennis--



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Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office 202-564-5637

-----Dennis Edwards/DC/USEPA/US wrote: -----

To: Philip Ross/DC/USEPA/US@EPA From: Dennis Edwards/DC/USEPA/US

Date: 06/02/2011 08:15AM

Cc: Velma Noble/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA Subject: Re: initial comments included... Re: Kemira application for registration





Dennis

Philip Ross---05/23/2011 09:58:41 AM---Attorney Client Communication Attorney Work Product

From: Philip Ross/DC/USEPA/US

To: Dennis Edwards/DC/USEPA/US@EPA

Cc: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Velma

Noble/DC/USEPA/US@EPA, Kim Wilson/DC/USEPA/US@EPA

Date: 05/23/2011 09:58 AM

Subject: Re: initial comments included... Re: Kemira application for registration

Attorney Client Communication Attorney Work Product Deliberative Privileged and Confidential Do Not Release

Dennis--

Thanks.

Phil

Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office 202-564-5637

Dennis Edwards---05/13/2011 10:39:02 AM---Attorney Client Communication Deliberative

From: Dennis Edwards/DC/USEPA/US To: Philip Ross/DC/USEPA/US@EPA

Cc: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Velma

Noble/DC/USEPA/US@EPA Date: 05/13/2011 10:39 AM

Subject: Re: initial comments included... Re: Kemira application for registration

Attorney Client Communication Deliberative Privileged and Confidential Do Not Release

Hi Phil,



Dennis

Philip Ross---04/27/2011 05:34:37 PM---Attorney Client Communication Attorney Work Product

From: Philip Ross/DC/USEPA/US

To: Dennis Edwards/DC/USEPA/US@EPA

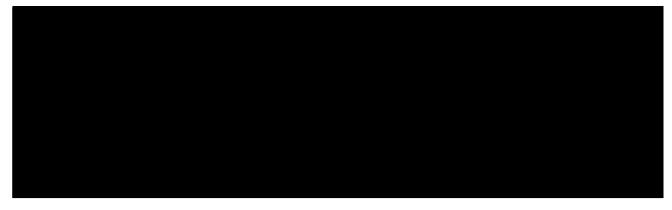
Cc: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Velma

Noble/DC/USEPA/US@EPA Date: 04/27/2011 05:34 PM

Subject: initial comments included... Re: Kemira application for registration

Attorney Client Communication Attorney Work Product Deliberative Privileged and Confidential Do Not Release

Dennis--



Thanks! [attachment "4 27 2011 pjr initial feedback to Dennis Edwards on Kemira.pdf" deleted by Dennis Edwards/DC/USEPA/US]

Phil

Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office 202-564-5637

Dennis Edwards---04/21/2011 11:36:51 AM---Hi Phil,

From: Dennis Edwards/DC/USEPA/US To: Philip Ross/DC/USEPA/US@EPA

Cc: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Tracy

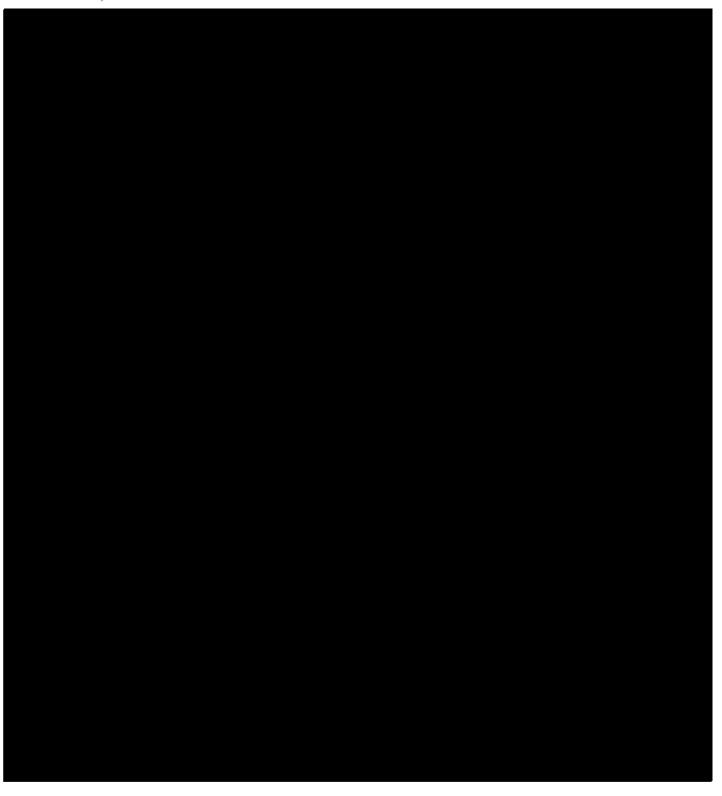
Lantz/DC/USEPA/US@EPA

Date: 04/21/2011 11:36 AM Subject: Kemira application for registration

Internal deliberative information



Re: initial comments included... Re: Kemira application for registration Dennis Edwards to: Philip Ross 06/02/2011 08:15 AM Cc: Velma Noble, Tracy Lantz



Dennis

Philip Ross

Attorney Client Communication Attorney Work P...

05/23/2011 09:58:41 AM

From:

Philip Ross/DC/USEPA/US

To:

Dennis Edwards/DC/USEPA/US@EPA

Cc:

Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Velma

Noble/DC/USEPA/US@EPA, Kim Wilson/DC/USEPA/US@EPA

Date:

05/23/2011 09:58 AM

Subject:

Re: initial comments included... Re: Kemira application for registration

Attorney Client Communication Attorney Work Product Deliberative Privileged and Confidential Do Not Release

Dennis--

Thanks.

Phil

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

Dennis Edwards

Attorney Client Communication Deliberative

05/13/2011 10:39:02 AM

From:

Dennis Edwards/DC/USEPA/US

To:

Philip Ross/DC/USEPA/US@EPA

Cc:

Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Velma

Noble/DC/USEPA/US@EPA

Date:

05/13/2011 10:39 AM

Subject:

Re: initial comments included... Re: Kemira application for registration

Attorney Client Communication Deliberative Privileged and Confidential Do Not Release



Dennis

Philip Ross Dennis Edwards Attorney Client Communication Attorney Work P...
Hi Phil,

04/27/2011 05:34:37 PM 04/21/2011 11:36:51 AM



initial comments included... Re: Kemira application for registration

Philip Ross to: Dennis Edwards

04/27/2011 05:34 PM

Cc: Joan Harrigan-Farrelly, Tracy Lantz, Velma Noble

Attorney Client Communication Attorney Work Product Deliberative Privileged and Confidential Do Not Release Preliminary reply from Phil Dennis sent more into on 5/13/11

Dennis--



- Esa

Thanks! 4 27 2011 pir initial feedback to Dennis Edwards on Kemira.pdf

Phil

Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office 202-564-5637

Dennis Edwards

Hi Phil,

04/21/2011 11:36:51 AM

From:

Dennis Edwards/DC/USEPA/US

To:

Philip Ross/DC/USEPA/US@EPA

Cc:

Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Tracy

Lantz/DC/USEPA/US@EPA

Date:

04/21/2011 11:36 AM

Subject:

Kemira application for registration

174

Internal deliberative information
Privileged attorney-client communication

From: Dennis Edwards/DC/USEPA/US

To: Philip Ross/DC/USEPA/US@EPA

Cc: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Veima Nobie/DC/USEPA/US@EPA, Tracy

Lantz/DC/USEPA/US@EPA

Date: Thursday, April 21, 2011 11:36AM Subject: Kemira application for registration

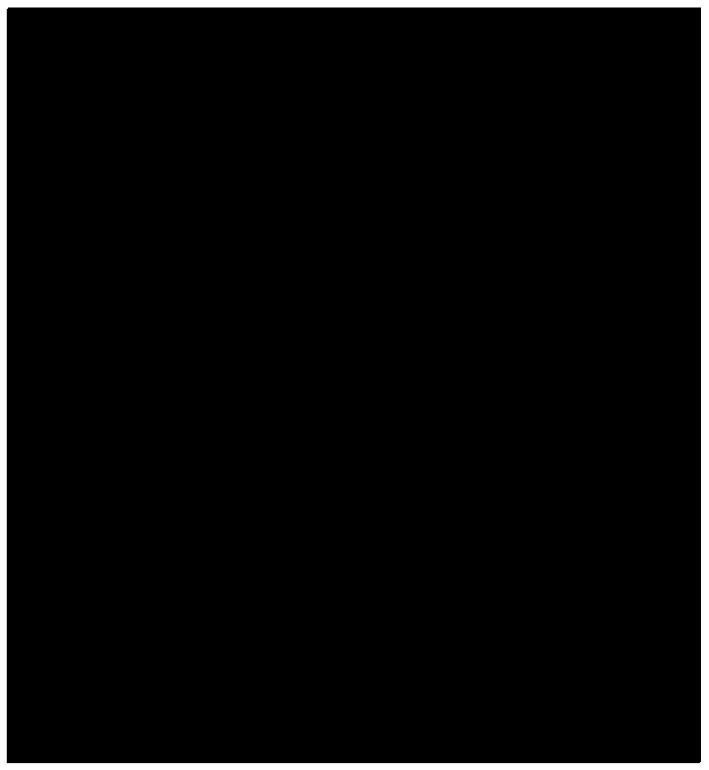
Privileged attorney-client communication



Kemira application for registration Dennis Edwards to: Philip Ross

Cc: Joan Harrigan-Farrelly, Velma Noble, Tracy Lantz

04/21/20 t1 t1:36 AM





Privileged attorney-client communication

Internal deliberative information

Product ingredient source information may be entitled to confidential treatment





Fw: Kemira application for registration Dennis Edwards to: Tracy Lantz, Velma Noble

04/16/20 t1 08:50 PM

Velma/Tracy

Dennis

Dennis <u>Edwards</u>, Unier

Regulatory Management Branch 1

Antimicrobials Division

703~308-8087

---- Forwarded by Dennis Edwards/DC/USEPA/US on 04/16/20 t1 08:44 PM ----

From:

Dennis Edwards/DC/USEPA/US

To:

Philip Ross/DC/USEPA/US 04/14/2011 07:47 PM (draft)

Date: Subject:

Kemira application for registration

Product ingredient source information may be entitled to confidential treatment

Fw: Kemira application for registration

Dennis Edwards to: Tracy Lantz, Velma Noble

04/16/2011 08:50 PM

Velma/Tracy



Dennis

Dennis Edwards, Chief Regulatory Management Branch 1 Antimicrobials Division 703-308-8087

---- Forwarded by Dennis Edwards/DC/USEPA/US on 04/16/2011 08:44 PM ----

 From:
 Dennis Edwards/DC/USEPA/US

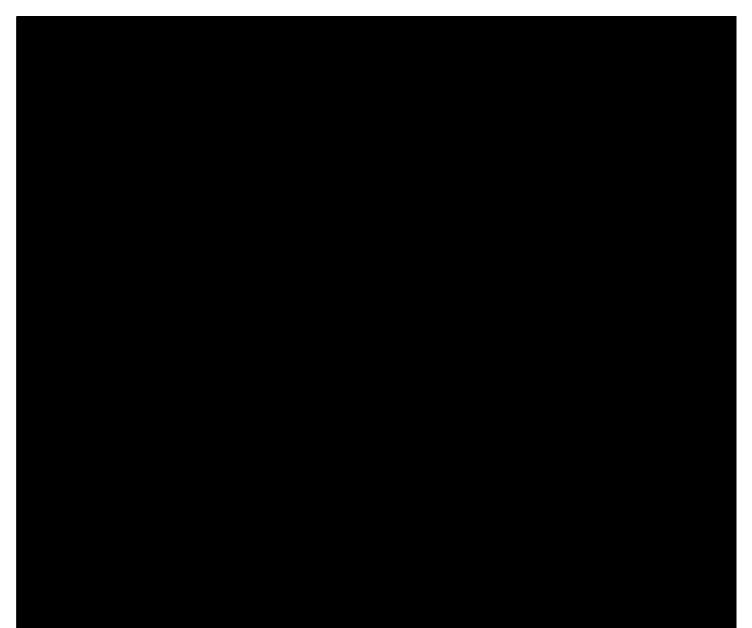
 To:
 Philip Ross/DC/USEPA/US

 Date:
 04/14/2011 07:47 PM

Subject: Kemira application for registration



Product ingredient source information may be entitled to confidential treatment



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Kemira Chemicals application for registration Dennis Edwards to: Philip Ross, Chris Kaczmarek Cc: Joan Harrigan-Farrelly, Tracy Lantz, Velma Noble

03/18/2011 11:30 AM

Phil,



Dennis/Tracy

Dennis Edwards, Chief Regulatory Management Branch 1 Antimicrobials Division 703-308-8087

Memorandum

Date.	03/04/11
To:	RM 31 , Regulatory Manager
From:	Information Services Branch, ITRMD
indicati	our receipt of this data submission is not at ion that MRIDs for the enclosed studies have ested to OPPIN.
from tl	e expect that it will be approximately 5 days ne above date before the study-level data is ble in OPPIN.
_	
-	you have any questions about this process, contact Teresa Downs (305-5363).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 2, 2011

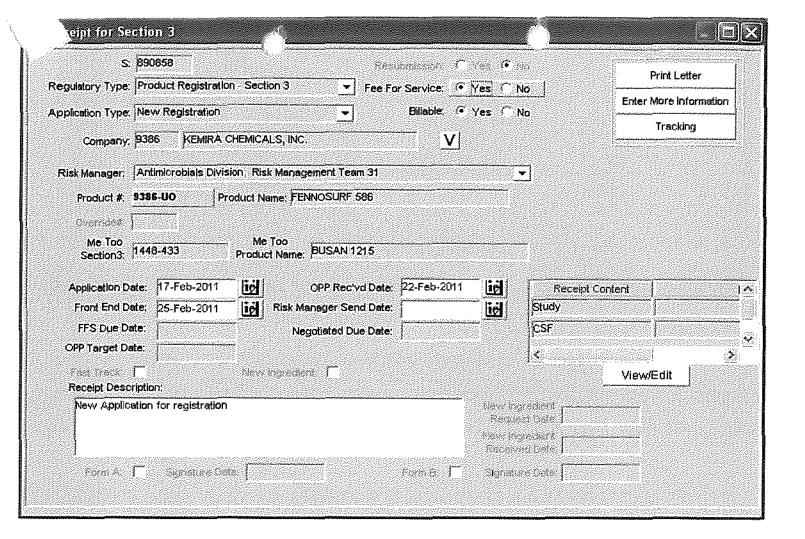
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DALE A. BAUER KEMIRA CHEMICALS, INC. 1950 VAUGHN ROAD KENNESAW, GA 30144-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 22-FEB-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



21-Day Screen Completed by Contractor

21-Day Expires on ______ 3-15-11

Jacket # 9386-U0 MRID# 483992

Content Screen: Recommend to Pass/Fail

86-5 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

VELMA Noble

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection per response for reregistration and special review activities, including time for rea estimate or any other aspect of this collection of information, including suggestion Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washingto	ading the instructions for reducing	tions and completing the necessary forms. Sead comments regarding burden the burden to: Director, Cottection Strategies Division (2822T), U.S.
Certification with	Respect to	Citation of Data
Applicant's/Registrant's Name, Address, and Telephone Number		EPA Registration Number/File Symbol
KEMIRA CHEMICALS INC 1000 PARKWOOD CIRCLE ATLANTA GA 30339		9386-U O
Active Ingredient(s) and/or representative test compound(s) AQUEOUS AMMONIA SOLUTION		Data 02-11-2011
General Use Pattern(s) (list all those claimed for this product using 40 CFF PAPER AND PAPER BOARD PROCESS WATERS	R Part 158)	Product Name FENNOSURF 586
NOTE: If your product is a 100% repackaging of another purchased EPA submit this form. You must submit the Formulator's Exemption Statement (A-registered pro (EPA Form 85	oduct labeled for all the same uses on your label, you do not need to 70-27).
I am responding to a Data-Call-In Notice, and have included with the used for this purpose).	nis form a list c	f companies sent offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DA	ATA SUPPOR	(Check one method only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	X the se	using the selective method of support (or cite-all option under elective method), and have included with this form a completed list a requirements (the Data Matrix form must be used).
SECTION II: G	ENERAL OFF	ER TO PAY
[Required if using the cite-all method or when using the cite-all option under	er the selective	method to satisfy one or more data requirements
old X i hereby offer and agree to pay compensation, to other persons, with m	egard to the a	proval of this application, to the extent required by FIFRA.
SECTION	I III: CERTIFIC	ATION
I certify that this application for registration, this form for reregistration, or registration, the form for reregistration, or the Data-Call-in response. In addition, if the application is supponed by all data in the Agency's files that (1) concern the properties ingredients in this product; and (2) is a type of data that would be required to be submapplication sought the initial registration of a product of identicat or similar composition	e cite-all option or as or effects of thi nitted under the d	s product or an identical or substantially similar product, or one or mora of the
I certify that for each exclusive use study cited in support of this registration permission of the original data submitter to cite that study.	on or reregistrati	on, that I am the original data submitter or that I have obtained the written
I certify that for each study cited in support of this registration or reregistration obtained the permission of the original data submitter to use the study in support of this study is in the public literature; or (e) I have notified in writing the company that submit 3(c)(1)(F) and for 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine	is application; (c)	d heve offered (i) to pay compensation to the extent required by sections
I certify that in atl instances where an offer of compensation is required, ci. $3(c)(1)(F)$ and/or $3(c)(2)(B)$ of FIFRA are available and will be submitted to the Agency that the Agency may initiate action to deny, cancel or suspend the registration of my p	y upon request. S	
t certify that the statements t have made on this form and att attachms misteading statement may be punishable by fine or imprisonment or both under		
	Date 02-17-20 t t	Typed or Printed Name and Title Colleen M Snyder Product Safety Expert-Blocides

EPA Form 8570-34 (12-2003) Electronic and Paper versions avaitable. Submit only Paper version.

Me-Too New Product Registration (PRIA-A532) Femosus: 586 (EPA REO. # 9368-UO) Data Submitters List 02/17/2011

DATA SUBMITTERS LIST

Buckman Laboratories, Inc. 1256 McLean Blvd Memphis TN 38108 901-278-0330 Busan 1215 BCMW EPA Reg. # 1448-433 EPA Reg. # 1448-432

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 21 December, 2011	EPA Reg No./File Symbol : 9386- UO	Page 1 of 3
Applicant's/Registrant's Name & Address:	End Use Product:	
Kemira Chemicals Inc, 1000 Parkwood Circle, Atlanta GA 30339	FENNOSURF 586	بلر

ngredient: Aqueous Ammonia So	lution					
Guideline Reference Number	Guideline Study Name	MRID Number		Submitter	Status	Note
PRODUCT CHEMISTRY						
830,1550 (61-1)	Product Identity / Disclosure of Ingredients	48399201	×	Kemira Chemicals Inc	OWN	
830.1600 (61-2a)	Beginning Malerials	48399201	×	Kemira Chemicals Iuc	OWN	
E30.1650 (61-2a)	Description of Formulation Prucess	48399201	×	Kemira Chemicals Inc	OWN	
830-1670 (61-2 b)	Discussion of Formation of Impurities	483 <u>992</u> 01	×	Kemira Chenticals Inc	OWN	
830.1700 (62-1)	Preliminary Analysis	48637101	×	Kemira Chemicals Inc	OWN	
830.1750 (62-2)	Certified Limits	483 99 201	×	Kemira Chemicals Inc	OWN	7.7
830.1800 (62-3)	Enforcement Analytical Method	48399201	×	Kemira Chemicals Inc	OWN	
830.6302 (63-02)	Calor	48399202	x	Kemira Chemicals Inc	OWN	
830.6303 (63-03)	Physical State	48399202	Х	Kerniro Chemicals Inc	OWN	
830,6304 (63-04)	Odor	48399202	X	Kemira Chenticals Inc	OWN	
830.6313 (63-13)	Stability	N/A	X	Kemîra Chenticals Inc		Not a TGAI/Mt Registratio
830.6314 (63-14)	Oxidation / Reduction	48399202	Х	Kemira Chemicals Inc	OWN	
830.6315 (63-15)	Flammability	48399202	Х	Kenira Chenicals Inc	OWN	
830.6316 (63-16)	Explodability	48399202	Х	Kemira Chemicals Inc	OWN	
Collen Ma	Snyder	Signature	Colleen	M Snyder Product Sat	Name and Title fety Expert	Date 21 DEC-2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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DATA MATRIX Date: 21 December, 2011 Applicant's/Registrant's Name & Address: Kemira Chemicals Inc, 1000 Parkwood Circle, Atlanta GA 30339 Ingredient: Jogradient: Aqueous Apmonia Solution

Note	Status	Submitter	MRID Number	Guideline Study Name	Guideline Reference Number
To be submitted				Storage Stability	830.6317 (63-17)
	OWN	Kemira Chemicals luc	48399202	Miscibility	830.63 19 (63-19)
To be submitted				Corrosion characteristics	830-6320 (63-20)
	OWN	Kemira Chemicals Inc	48399202	Dielectric breakdown voltage	830.6321 (63-21)
	OWN	Kemira Chemicals Inc	48690401	рН	830.7000 (63-12)
Not a TGAI/MU Registration		Kemira Chemicals Inc	N/A	UV/Visible Spectra	830.7050
	OWN	Kemira Chemicals Inc	48690401	Viscosity	830.7100 (63-18)
WAIVER	Waive	Kemira Chemicals Inc	N/A	Melting point	830.7200 (63-5)
Not a TGAI/MU Registration		Kemira Chemicals Inc	N/A	Boiling point	830.7220 (63-6)
	OWN	Kemira Chemicals Inc	48690401	Density / relative density / bulk density	830.7300 (63-7)
Not o TGAI/MU Registration		Kemira Chemicals Inc	N/A	Dissociation constant in water	830.7370 (63-10)
Not a TGA L/MU Registration		Kemira Chemicals Inc	N/A	Octanol / water partition coefficient	830.7570 (63-11)
Not a TGAI/MU Registration	-	Kemira Chemicals Inc	N/A	Water solubility	830,7860 (63-8)
Not a TGAI/MU Registration		Kemira Chemicals Inc	NA	Vapor pressure	830.7950 (63-9)
Date 21DEC-2011	Name and Title	Colleen M Snyder Product Safe	Signature		Collen M Snyo

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	DATA N	MATRIX			
Oate: 21 December, 2011			EPA Reg No./File Symbol 9386-UO	Page 3 of 3	
Applicant's/Registrant's Name & Address: Kemira Chemicals Inc, 1000 Parkwood Circ	ile, Atlanta GA 30339		End Use Product: Fennosurf 586	,,,,,, _, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	**
ingredient: Ingredient: Aqueous Ammonia Solut	ion				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY					
870.1100 (81-1)	Acute Oral Toxicity	464351-08	Buckman Laboratorics	Offer to Pay	
870.1200 (81-2)	Acute Dermal Toxicity	464351-09	X Buckman Laboratorics	Offer to Pay	
870.1300 (81-3)	Acute Inhalation Toxicity	464351-10	X Buckman Laboratories	Offer to Pay	
870.2400 (81-4)	Acute Eye Irritation	464351-11	Buckman Laboratories	Offer to Pay	
870.2500 (81-5)	Acute Dermal Irritation	464351-12	Buckman Laboratories	Offer to Pay	<u> </u>
870,2600 (81-6)	Skin Sensitization	464351-13	Buckman Laboratories	Offer to Pay	
Collee on Suco	/0.0	Signature	Colleen M Snyder Product Sa	Name and Title	

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Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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SUPPORTING DATA MATRIX ON SOURCE MATERIAL Date: 21 December, 2011 Applicant's/Registranl's Name & Address: Kemira Chemicals Inc, 1000 Parkwood Circle, Atlanta GA 30339 SUPPORTING DATA MATRIX ON SOURCE MATERIAL EPA Reg No./File Symbol : 9386- UO Product- Aqueous Ammonia Solution

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Not
PRODUCT CHEMISTRY- GROUP A			1		
830.1550 (61-1)	Product Identity / Disclosure of Ingredients	464351-02/464351-14 ⁷	Buckman Laboratories	Offer To Pay	
830.1600 (61-2a)	Beginning Materials	464351-02 ^X	Buckman Laboratories	Offer To Pay	
830.1620 (61-2a)	Description of Production Process	4643512-14 ^X	Buckman Laboratories	Offer To Pay	
830,1650	Description of Formulation (Manufacturing) Process	4741 t t-02 ^X	Buckman Laboratories	Offer To Poy	
830-1670 (61-2b)	Discussion of Formation of Impurities	164351-02/464351-14	Buckman Laboratories	Offer To Pay	
830,1700 (62-1)	Preliminary Analysis	464351-14/4741110 1 X	Buckman Laboratories	Offer To Pay	
830,1750 (62-2)	Certified Limits	464351-02/464351-14 ×	Buckman Laboratories	Offer To Pay	
830.1800 (62-3)	Enforcement Analytical Method	464351-027464351-147 464580-01X	Buckman Laboratories	Offer To Pay	
830.1900 (64-1)	Submittal of Samples	***************************************	Buckman Laboratories	Offer To Pay	
PRODUCT CHEMISTRY- GROUP B					
830.6302 (63-02)	Color	464700-01 ^X	Buckman Laboratories	Offer To Pay	
830.6303 (63-03)	Pltysical State	464700- 0 1X	Buckman Laboratories	Offer To Pay	
830.6304 (63-04)	Odor	464700-01 [×]	Buckman Laboratories	Offer To Pay	
830.6313 (63-13)	(Accelerated) Stability	464351-04 ^X	Buckman Laboratories	Offer To Pay	
Co Cury Sno	der	Signature	Colleen M Snyder Product Sa	Name and Title fety Expert	21DEC-20

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Form Approved OMB No. 2070-0060

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	SUPPORTING DATA MATE	RIX ON SOURCE N	/ATERIAL							
Date: 21 December, 2011			EPA Reg No./File Symbol 9386- UO		Page 2 of 3					
Applicant's/Registrant's Name & Address: Kern	ira Chemicals Inc, 1000 Parkwood Circle, Atla	anta GA 30339	Product~ Aqueous Ammonia Solutio	/						
Ingredient: Ingredient: Aqueous Ammonia	a Solution (5302) TO SUPPORT END USE PROD	UCT FENNOSURF S	86							
Guldeline Reference Number Guldeline Study Name MRID Number Submitter Status Note										
PRODUCT CHEMISTRY- GROUP B cont.		· · · · · · · · · · · · · · · · · · ·								
830.6317 (63-17)	Storage Stability	4643\$1-04	Buckman Laburatorics	Offer To Pay						
830.7000 (63-12)	рН	464700-01	Bucknian Laboratories	Offer To Pay						
830,7050	UV/Vísible Spectra	cited	Buckman Laboratories	Offer To Pay						
830,7220 (63-6)	Boiling point	464700-01 ^X	Buckman Laboratories	Offer To Pay						
830.7300 (63-7)	Density / relative density / bulk density	464700-01 ^X	Buckman Laboratories	Offer To Pay						
830.7370 (63-10)	Dissociation constant in water	464700-0 t ^X	Buckman Laboratories	Offer To Pay						
830.7570 (63-11)	Octanol / water partition coefficient	cited	Buckman Laboratories	Offer To Pay						
830.7860 (63-8)	Wuter solubility	citcd	Buckman Laboratories	Offer To Pay						
830.7950 (63-9)	Vapor pressure	464700-01 ^X	Buckman Laboratories	Offer To Pay						
Collen M S	nyder	Signature	Colleen M Snyder Product S	Name and Title Safety Expert						

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	SUPPORTING DATA MATE	RIX ON SOURCE N	/ATERIAL		
te: 21 De c ember, 201 1			EPA Reg No./File Symbol 9386-UO		Page 3 of 3
plicant's/Registrant's Name & Address: emira Chemicals Inc, 1000 Parkwood Circle, Atlanta GA 30339		Product- Aqueous Ammonia Solution	- L		
gredient: Ingredient: Aqueous Ammonia	Solution (5302) TO SUPPORT END USE PRODU	JCT FENNOSURF 5	<u>86</u>		
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Not
TOXICOLOGY					
870.1100 (81-t)	Acute Oral Toxicity	464351-08	Buckman Laboratories	Offer to Pay	
870.1200 (81-2)	Acute Dermal Toxicity	4643\$1-09\	Buckman Laboratories	Offer to Pay	
870.1300 (81-3)	Acute Inhalation Toxicity	4643 <i>5</i> 1-10')	Bucktnan Laboratories	Offer to Pay	
870.2400 (81-4)	Acute Eye Irritation	464351-117	Buckman Laboratories	Offer to Pay	
870.2500 (81-5)	Acute Dermal Irritation	464351-12	Buckman Laboratories	Offer to Pay	
870.2600 (81-6)	Skin Sensitization	464351-13	Buckman Laboratories	Offer to Pay	
850.1075	Acute Exposure Aquatic (Blue Gill)	4643 <i>5</i> 1-05 ₃	Buckman Laboratories	Offer to Pay	
850.1075	Acute Exposure Aquatic (Rainbow Trout)	464351-06	Buckman Lahoratories	Offer to Pay	
850.1010	Acute Exposure Aquatic (Daplinia Magna)	464351-07	1448-432 Buckman Laboratories	Offer to Pay	
850.2100	Acute Oral Avian (bird)	464405-01 ^X	148-433 Buckman Laboratories	Offer to Pay	
	Mammalian Environmental Fate & Fute	464581-01/	Buckman Laboratories	Offer to Pay	
Collen m S	n der	Signature	Colleen M Snyder Product Sa	Name and Title fety Expert	21DEC-201

EPA Form \$570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Summary Information For Study 46440501

MRID:

46440501

Citation Reference:

Gallagher, S.; Beavers, J. (2004) BSN 1215: An Acute Oral Toxicity Study with the

Northern Bobwhite. Project Number: 210/122. Unpublished study prepared by Wildlife

International, Ltd. 34 p.

86-5 Status:

Pass (25-Aug-2010)

Author:

Gallagher, S. Beavers, J.

Content Category:

Complete primary report -- experimental research

Receipt Date:

07-Jan-2005

Laboratory Project #: 210/122

Accession #:

Products Tested:

1448-UGG

(-433)

Status:

DP #:

Ingredients

PC Code	CAS#	ingredient Name					
005302 7664-41-7		Ammonia					
Total Rows: 1							

Laboratory

Laboratory #	Laboratory Name
1448	BUCKMAN LABORATORIES INC.
959498	Wildlife International, Ltd.
Total Rows: 2	

EPA Home | OPP-Home | Search | Help

Last updated on December 22, 2009, Version 1.10 https://prism.epa.gov/pls/prism10p

Summary Information For Study 48690401

MRID: 48690401

Citation Reference: Wo, C. (2011) Fennosurf 586: Physical and Chemical Characteristics: pH, Viscosity,

and Density/Relative Density. Project Number: 32513, P801. Unpublished study

prepared by Eurofins/Product Safety Laboratories. 14p.

86-5 Status:

Author: Wo, C.

Content Category: Complete primary report – experimental research

Receipt Date: 05-Dec-2011

Laboratory Project #: 32513, P801

Accession #:

Products Tested: 9386-UO

Status:

DP #: 394455

Ingredients

PC Code CAS#		Ingredient Name					
005601 7783-20-2		Ammonium sulfate					
Total Rows: 1							

Laboratory

Laboratory #	Laboratory Name
9386	KEMIRA CHEMICALS, INC.
85020	Eurofins/Product Safety Laboratories
Total Rows: 2	

EPA Home | OPP-Home | Search | Help

Last updated on December 22, 2009, Version 1.10 https://prism.epa.gov/pls/prism10p

Study Information For Product Registration - Section 3 1448-432

MRID	Citation	Receipt Date
46435100	Buckman Laboratories, Inc. (2004) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of BCMW and Busan 1215. Transmittal of 12 Studies.	23- Dec- 2004
46435102	Watson, C. (2004) Product Chemistry for Busan 1215 Product Identity, Composition and Analysis. Unpublished study prepared by Buckman Laboratories, Inc. 13 p.	23- Dec- 2004
46435104	Wo, C. (2004) Accelerated Storage Stability Study: Busan 1215. Project Number: 15281, P802. Unpublished study prepared by Product Safety Labs. 16 p.	23- Dec- 2004
/ 46435105	Palmer, S.; Kendall, T.; Krueger, H. (2004) Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Bluegill (Lepomis macrochirus): Final Report: (Busan 1215). Project Number: 210A/103B. Unpublished study prepared by Wildlife International, Ltd. 38 p.	23- Dec- 2004
<i>J</i> 46435106	Palmer, S.; Kendall, T.; Krueger, H. (2004) Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Final Report: (Busan 1215). Project Number: 210A/104. Unpublished study prepared by Wildlife International, Ltd. 39 p.	23- Dec- 2004
√ 46435107	Palmer, S.; Kendall, T.; Krueger, H. (2004) Aqueous Ammonia Solution: A 48-Hour Flow-Through Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report: (Busan 1215). Project Number: 210A/102. Unpublished study prepared by Wildlife International, Ltd. 39 p.	23- Dec- 2004
46435108	Merkel, D. (2004) Acute Oral Toxicity Up and Down Procedure in Rats: Busan 1215. Project Number: P320/UDP, 15282. Unpublished study prepared by Product Safety Labs. 15 p.	23- Dec- 2004
46435109	Merkel, D. (2004) Acute Dermal Toxicity Study in Rats - Limit Test: Busan 1215. Project Number: P322, 15283. Unpublished study prepared by Product Safety Labs. 15 p.	23- Dec- 2004
√ 46435110	Merkel, D. (2004) Acute Inhalation Toxicity Study in Rats - Limit Test: Busan 1215. Project Number: 15284, P330. Unpublished study prepared by Product Safety Labs. 22 p.	23- Dec- 2004
46435111	Merkel, D. (2004) Primary Eye Irritation Study in Rabbits: Busan 1215. Project Number: P324, 15285. Unpublished study prepared by Product Safety Labs. 15 p.	23- Dec- 2004
46435112	Merkel, D. (2004) Primary Skin Irritation Study in Rabbits: Busan 1215. Project Number: P326, 15286. Unpublished study prepared by Product Safety Labs. 15 p.	23- Dec- 2004
46435113	Merkel, D. (2004) Dermal Sensitization Study in Guinea Pigs (Buehler Method): Busan 1215. Project Number: 15287, P328. Unpublished study prepared by Product Safety Labs. 23 p.	23- Dec-

K	egistration Quer	y results	
			2004
	46435114	Watson, C. (2004) Product Chemistry: Manufacture, Preliminary Analysis, Analytical Method, Certified Limits: BCMW. Unpublished study prepared by Buckman Laboratories, Inc. 44 p.	23- Dec- 2004
	46458000	Buckman Laboratories, Inc. (2005) Submission of Product Chemistry Data in Support of the Application for Registration of BCMW. Transmittal of 1 Study.	31-Jan- 2005
	46458001	Kendall, T.; Nixon, W. (2005) Analytical Method Verification for the Determination of Aqueous Ammonia Solution in Freshwater. Project Number: 210C/101, 210/070804/MV/FW/100P/206. Unpublished study prepared by Wildlife International, Ltd. 38 n	31-Jan- 2005
•	46458100	Buckman Laboratories, Inc. (2005) Submission of Toxicity, Exposure and Risk Data in Support of the Applications for Registration of BCMW and Busan 1215. Transmittal of 1 Study.	31-Jan- 2005
	46458101	Watson, C. (2005) Mammalian Toxicology and Environmental Fate and Effects Data: BCMW/Busan 1215: Supplemental Report. Unpublished study prepared by Buckman Laboratories, Inc. 832 p.	31-Jan- 2005
	464/0000	Buckman Laboratories, Inc. (2004) Submission of Product Chemistry Data in Support of the Application for Registrations of BCMW and BUSAN 1215. Transmittal of 2 Studies.	14-Feb- 2005
/	46470001	Watson, C. (2004) Product Chemistry for BCMW: Physical/ Chemical Properties. Unpublished study prepared by Buckman Laboratories Inc. 16 p.	14-Feb- 2005
\	46470002	Watson, C. (2004) Product Chemistry for BUSAN 1215: Physical/ Chemical Properties. Unpublished study prepared by Buckman Laboratories Inc. 16 p	14-Feb- 2005
	47411100	Buckman Laboratories International, Inc. (2008) Submission of Product Chemistry Data in Support of the Amended Registration of BCMW. Transmittal of 2 Studies.	24- Apr- 2008
	47411101	Watson, C.; Proulx, G.; Zou, S. (2008) Revised Product Chemistry: Manufacture, Preliminary Analysis, Analytical Method, Certified Limits: WW. Unpublished study prepared by Buckman Laboratories, Inc. 90 p.	24- Apr- 2008
	47411102	Watson, C.; Proulx, G.; Zou, S. (2008) Product Chemistry for BCMW From the Revised Manufacturing Process Physical / Chemical Properties. Unpublished study prepared by Buckman Laboratories Inc. 14 p.	24- Apr- 2008
	Total Row	s: 23	

PRIA 2 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) 3/23/09

21 Day Screen Start Date:	2-2	2-11		_
Experts In-Processing Signature:	ME	HARRINGTON	Date 2-28-1/	Fee Paid: Yes 🗸
Division management contacted on i	ssues	NoYes	Date	

EPA	Reg. Number: 9386 - UO	EPA Receipt Date:	Z - 2	22-	11			
	Items for Review							
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type							
2	Confidential Statement of Formula all dated (EPA Form 8570-4) (Link to form	-	igned, a	nd	X			
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)							
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)							
	Certificate and data matrix consistent							
		applicant is relying on data that are compensable, is the offer bay statement included. (see Footnote B)						
4	If applicable, is there a letter of Authoriz Formulator's Exemption Statement (Formulator and signed (N/A if source is to be a supplementation of the source of the supplementation of	EPA Form 8570-27) (Link	to form	,			λ	
	Data Matrix (EPA Form 8570-35) (Lincopies (PR 98-5) (Link to PR 98-5) comrepack)		100%	nal	X			
5	a) Selective Method (Fee category expe	erts use)	yes ×	no				
	b) Cite-All (Fee category experts use)							
	c) Applicant owns all data (Fee category experts use)							
6	5 Copies of Label (link to							

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X	
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)	**************************************	7
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)		X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C. a) List study (or studies) not included with application		

Comments:

* A.I. + % composition are available in opposition are available in opposition are available in opposition & CSF is approved for food use.

* All essential forms are present if free of error.

* All essential forms are present if free of error.

* Data Package is approved.

* Jackel approved.

MRID 483992

* N/A – Not Applicable

IK 8-4813

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to

http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNÍTED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

February 28, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-445675

EPA File Symbol or Registration Number: 9386-UO

Product Name: FENNOSURF 586 EPA Receipt Date: 22-Feb-2011 EPA Company Number: 9386

Company Name: KEMIRA CHEMICALS, INC.

DALE A. BAUER KEMIRA CHEMICALS, INC. 1950 VAUGHN ROAD KENNESAW, GA 30144-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A532

UNREGISTERED SOURCE OF ACTIVE INGREDIENT; NEW PRODUCT; CITE-ALL DATA CITATION EXCEPT FOR PRODUCT CHEMISTRY; IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT; PRODUCT CHEMISTRY DATA SUBMITTED; REGISTERED ACTIVE INGREDIENT;

Please remit payment in the amount of: \$2,977 (\$4,631 fee minus \$1,654 previously paid) to:

By USPS:

USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 979074 St. Louis, MO 63197-9000 A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

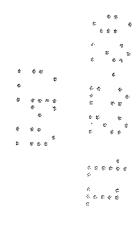
Sincerely, Teresa Downs

Front End Processing Staff

Information Technology & Resources Management Division



Document Processing Desk (REGFEE)
Mr. Marshall Swindell Product Manager #33
Office of Pesticide Programs (7504P)
Room S-4900 One Potomac Yard-South Building
2777 South Crystal Drive
Arlington VA 22202-4501



Re: Me-Too New Product Registration (PRIA-A531) Fennosurf 586 (EPA REG. # 9368-___)

Dear Mr. Swindell:

Attached to this letter are the required application documents for this End-Use product registration. Included are:

- One (1) Copy: Application for Reregistration EPA Form 8570-1
- Two (2) Copies: Confidential Statement of Formula
- Five (5) Copies: Draft Product Label
- One (1) Copy: Confidential Statement of Formula (Basic Formulation)
- One (1) Copy: Data Matrix (Product Specific)
- One (1) Copy: Citation with Respect to Data
- Product Chemistry Group A & B with Confidential Appendix

It is the intention of the Antimicrobial End-Use (Me-Too) application to use the Selective-Cite All method of data citation. Fennosurf 586 is substantially similar to Buckman Laboratories Busan 1215 (EPA Reg.# 1448-433). A Data Matrix has been included. It is also the intention of this application to rely on the breath of data in the public domain regarding the use of ammonia and aqueous ammonia products in the municipal, drinking and swimming pool water arenas. Ammonium sulfate and aqueous ammonia solutions are well documented for risk assessments by EPA, FDA and ATSDR, to name a few. EPA has stated, "the chemistry of ammonia in water (i.e, aqueous ammonia) has been extensively studied and well understood." The Agency has placed ammonium sulfate on the Inerts 4B List of no or minimal concern due to this knowledge of ammonia based chemistries.

KEMIRA CHEMICALS, INC.

Me-Too New Product Registration
(PRIA-A531)
Fennosurf 586 (EPA REG. # 9368-__)
Cover Ltr 02/17/2011

EPA has concluded there to be no ecotoxicity concerns with these products and Kemira's Fennosurf 586 meets these exposure risk decisions with a "closed feed" system.

Please let me know if you need additional information.

Collen M Snyder

Best regards,

Colleen M Snyder

Enclosure

Document Processing Desk (REGFEE)
Mr. Marshall Swindell Product Manager #33
Office of Pesticide Programs (7504P)
Room S-4900 One Potomac Yard-South Building
2777 South Crystal Drive
Arlington VA 22202-4501

Re: Me-Too New Product Registration (PRIA-A531) Fennosurf 586 (EPA REG. # 9368-_)

Dear Mr. Swindell:

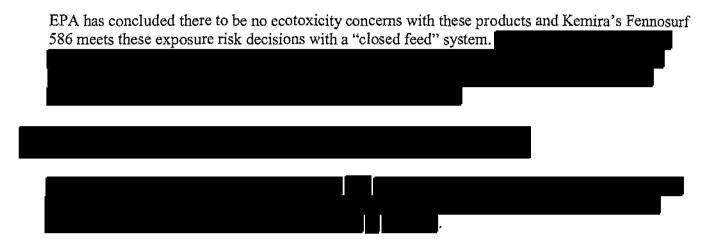
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- One (1) Copy: Confidential Statement of Formula (Basic Formulation)
- One (1) Copy: Data Matrix (Product Specific)
- One (1) Copy: Citation with Respect to Data
- Product Chemistry Group A & B with Confidential Appendix

It is the intention of the Antimicrobial End-Use (Me-Too) application to use the Selective-Cite All method of data citation. Fennosurf 586 is substantially similar to Buckman Laboratories Busan 1215 (EPA Reg.# 1448-433). A Data Matrix has been included. It is also the intention of this application to rely on the breath of data in the public domain regarding the use of ammonia and aqueous ammonia products in the municipal, drinking and swimming pool water arenas. Ammonium sulfate and aqueous ammonia solutions are well documented for risk assessments by EPA, FDA and ATSDR, to name a few. EPA has stated, "the chemistry of ammonia in water (i.e, aqueous ammonia) has been extensively studied and well understood." The Agency has placed ammonium sulfate on the Inerts 4B List of no or minimal concern due to this knowledge of ammonia based chemistries.

KEMIRA CHEMICALS, INC.

1950 Vaughan Road Kennesaw, GA 30144 TELEPHONE 678-819-4566 dd TOLL FREE 800-347-1542 FAX 678-819-4625 email Colleen.Snyder@Kemira.com



Please let me know if you need additional information.

Collen M Snyder

Best regards,

Colleen M Snyder

Enclosure

TRANSMITTAL PAGE

Submitter:	1950 Vaughn	Kemira Chemicals, Inc. 1950 Vaughn Road Kennesaw, GA 30144						
Regulatory Action:	(EPA File Syn	Fennosurf 586 (EPA File Symbol No. 9386-XX) Me-Too New Product Registration (PRIA-A531)						
Transmittal date:	011							
List of submitted studie	<u> </u>							
• Volume I. Administrative Materials (Cover letter, Forms, Labels, Waivers)								
MRID#								
Volume II. Product Chemistry Group A Public								
MRID#48399201								
Volume II. Product Chemistry Group A CONFIDENTIAL ATTACHMENT								
MRID#								
Volume II Product Chemistry Group B Public								
MRID#		48399202						
Company Official:	Colleen M Snyder	(Signature)	Snyder					
Company Name:	Kemira Chemicals Inc							
Company contact:	Colleen M Snyder	678-819-4566						

ORIGINAL

FENNOSURF 586 package

Mr. Marshall Swindell Product Manager #33 Office of Pesticide Programs US Environmental Protection Agency Antimicrobial Division (7504P) 1200 Pennsylvania Avenue NW Washington DC 20460

Courier:

Document Processing Desk (REGFEE) Mr. Marshall Swindell Product Manager #33 Office of Pesticide Programs (7504P) Room S-4900 One Potomac Yard-South Building 2777 South Crystal Drive Arlington VA 22202-4501

Package to include:

Vol I

- Transmittal Page
- Cover Letter
- One (1) Copy: Application for Registration EPA Form 8570-1
- Two (2) copies: Confidential Statement of Formula
- One (1) Copy: Confidential Statement of Formula for an alternate formulation
- One (1) Copy: Data Matrix-End Use Product Specific
- One (1) Copy: Citation with Respect to Data
 - o Data Submitters List
- Five (5) copies: Draft Product Label

Vol II Product Chemistry Group A Non-Confidential

Vol II Product Chemistry Group A Confidential Appendix

Vol II Product Chemistry Group B

TRANSMITTAL PAGE

Submitter:	Kemira Chem 1950 Vaughn Kennesaw, G	Road					
Regulatory Action:	(EPA File Syr	Fennosurf 586 (EPA File Symbol No. 9386-XX) Me-Too New Product Registration (PRIA-A531)					
Transmittal date:	February 17, 2	February 17, 2011					
List of submitted studie	<u>s:</u>						
 Volume I. Administrative Materials (Cover letter, Forms, Labels, Waivers MRID#							
Volume II. Product Chemistry Group A Public							
MRID#							
Volume II. Product Chemistry Group A CONFIDENTIAL ATTACHMENT							
MRID#							
Volume II Product Chemistry Group B Public							
MRID#							
Company Official:	Colleen M Snyder	Collen M Snyder (Signature)					
Company Name:	Kemira Chemicals Inc						
Company contact:	Colleen M Snyder	678-819-4566					

Please read instructions on reverse side before completing form.

⊕EPA	United States Environmental Protection Agen Washington, DC 2			20460		X Registration Amendment Other:		ment	OPP Identifier Number	
			Applicat	ion for P	esticide - Se					
1. Company/Produc	t Numb	er 9386-XX			2. EPA Product M	_	 _		3. Proposed	Classification
4. Company/Produc	t (Name			***	Swindell PM# 33				None None	Restricted
5. Name And Addte	ss Of A	pplicant (Include ZIP)			6. Expedited R					
		Chemicals, Inc.	•		(b)(i), my produc					
í		ughn Road			to: EPA Reg. No.		1448-	433		
Kei	nnesa	w, GA 30144			EPA Reg. No1448-433					
Спес	k if th/s	is a new address	<u></u>	<u></u> -	Product Name	B	usan 1	1215		
				Sec	ction				· · · <u>- · · · · · · · · · · · · · · · ·</u>	
Amendment -	Explain	below.			Final Printe			nse to		
Resubmission	in respo	onse to Agency letter of	dated		Agency lett X "Me Too" Ap					
		_			Other - Exp	-				
Notification – E										- · · · · ·
Explanation: Use	addition	nal page(s) if necessa	iry. (For section	on I and Sec	ction II.) To change	the sou	rce(s)	of active	ingredients	for this product.
PRIA assessmer	nt: Ca	tegory A531; Fe	e: \$1,654	; Decisior	n Time: 4 mont	ths. En	nail:	Colleen	.Sny d er@k	(emira.com
		STRUCTION: 2 ONTAINER SIZE)11-COR	RRECTION T	O API	PLIC	ATIO	N FORN	<u>DATED</u>
				Sec	tion III					
1. Material This Proc	Juct Will	Be Packaged In:								
Child Resistant Pack	kaging	Unit Packaging		Water	Soluble Packaging		2. Ty	pe of Co	ntainer	***************************************
Yes*		Yes		Yes				Met		
⊠ No		⊠ No		No No				∐ Plas Glas		
* Certification n be submitted	nust	If "Yes" Unit Packaging wgt.	No, per Containe				Pap			
De Sanin		Office monways.gg					er (Specify) _			
3. Location of Net Co	ontents	Information		Retail Contai		5, 1			l Directions	
⊠ Label [Con	ntainer	275 gal, IJ	BC (Tote I	Bin)			On Labe On Labe	l ling accompar	nying product
6. Manner in Which L	abel is	Affixed to Product	Lithogra Pager 9 Stencile	r glued Unite:						
		*************************************	L		tion IV		*********			
1. Contact Point (Cor	mplete i	tems directly below fo	r identificatio			if necessa	ary, to p	nocess ti	nis application	.)
Name	•			· · · · · · · · · · · · · · · · · · ·			ine No. (Include Area Code)			
Colleen M Snyder			Product Safety Expert-Biocides				678-819-4566			
Certification 6. Date Application Received										
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or (Stamped)										
imprisonment or both under applicable law. 2. Signature 3. Title										
Collente Sonder				Product Safety Expert-Biocides						
4. Typed Name 5. Dat				5. Date					7	
Colleen M Snyder				DECEMBER 20, 2011						

